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Report of the Massachusetts Task Force On Organ Transplantation

Presented to the Commissioner of Public Health and Secretary of Human Services

MAR 15 1985

October 1984

George J. Annas
Chairman

REPORT OF THE MASSACHUSETTS TASK FORCE

ON

ORGAN TRANSPLANTATION

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REPORT OF THE MASSACHUSETTS TASK FORCE

ON

ORGAN TRANSPLANTATION

Presented to the Commissioner of Public Health and the
Secretary of Human Services
Commonwealth of Massachusetts

October 1984

Copies of this Report may be obtained from the

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Commonwealth of Massachusetts
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Chief, Health Law Section

October 18, 1984

Bailus Walker, Jr, Ph.D., M.P.H.
Commissioner of Public Health
Commonwealth of Massachusetts
150 Tremont Street
Boston, MA 02111

Dear Commissioner Walker:

I am pleased to transmit the Final Report of the Task Force on Organ Transplantation. The Report represents more than a year of work by the 17 members of the Task Force, and assistance of almost 100 individuals and groups who gave us their views.

I believe it is remarkable, given the composition of the Task Force, and the stake that many members and the organizations they represent have in organ transplantation, that the Task Force adopted all of its recommendations unanimously. This speaks very highly of the Task Force members, and the spirit of serious reflection and the willingness to explore new perspectives and to compromise, which characterized the workings of the group. Accordingly, while we do not pretend that our recommendations are the "final word", they represent conclusions arrived at through an open, public process and consideration of all reasonable policy options. We all trust that you, the Public Health Council, and other public officials will take this Report very seriously, and use its Recommendations in making decisions regarding the introduction of organ transplantation, and other extreme and expensive technologies, into the Commonwealth.

On behalf of all of the members of the Task Force, I'd like to thank you for giving us the opportunity to contribute to public understanding of this complex issue, and to the development of a sound public policy regarding it.

Sincerely,

George J. Annas

cc: Philip W. Johnston
Secretary of Human Services

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REPORT OF THE MASSACHUSETTS
TASK FORCE ON ORGAN TRANSPLANTATION

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Finally we would like to acknowledge the special contribution of Professor Leonard Glantz of Boston U. School of Public Health who critically reviewed our work as it progressed, and Lynn Pitts who had sole responsibility for final preparation of both the draft and final report.

SUMMARY OF RECOMMENDATIONS

1. Liver and heart transplantation should be introduced into the Commonwealth in a controlled, phased manner that provides the opportunity for effective evaluation and review of its clinical, social, and economic aspects by a publicly-accountable body after an initial phase ("Phase I") of 2-3 years of limited transplantation.

2. The decision of when extreme and expensive medical technologies, like heart and liver transplantation, should be generally available should be made only after the clinical, social, and economic consequences of introducing the procedure, including cost-effectiveness, ethical implications, and long term effects on society, are studied and reviewed by a publicly-accountable body.

3. In making a decision regarding an application for a determination of need (DON) for heart and liver transplantation, the Public Health Council should attempt to minimize and track the total incremental cost of adding these procedures to the health care system.

4. Until such time as there is reasonably reliable data on the need for, costs of, and outcomes of liver and heart transplantation (end of Phase I) hospitals proposing to do these procedures in the Commonwealth should not be given a certificate of need unless they agree to (1) support the operating expenses for heart and liver transplantation within current reimbursement limits set by the hospital's maximum allowable cost under Ch. 372 of the Acts of 1982;* (2) collect evaluative data on the costs, outcomes, and displacements caused by transplant candidates who receive transplants as well as those who do not, in a manner approved by the Department of Public Health, and agree to make this data available to the Department and an independent evaluation group; and (3) have its protocols reviewed, approved and monitored by its Institutional Review Board (IRB), or by a special review board set up for this purpose by the Department of Public Health.

5. Patient selection criteria should be public, fair, and equitable. Primary screening should be based on medical suitability criteria made available to the public which is designed to offer transplantation to those who can benefit the most from it in terms of probability of living for a significant period of time with a reasonable prospect for rehabilitation. If there are insufficient resources to transplant all who can so benefit, selection from the medically-suitable group should be based primarily on a first-come, first-served basis. The selection criteria and process should be filed with a publicly-accountable body.

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*Provided that an exception may be granted for expenditures that are unique to organ transplantation: the cost of the organ itself and the cost of Cyclosporin A.

6. If more than one hospital is granted a certificate of need to do heart or liver transplantation, all hospitals so involved should be required to coordinate services in a way that comes as close as possible to a single, integrated medical service. Each hospital should be able independently to demonstrate either its ability to perform the procedure, or to act in concert with the other hospitals in a particular aspect of the procedure. All hospitals should establish and use a single set of patient selection and treatment protocols, agree to joint publication of research results, use of a common patient recipient pool and a common organ procurement pool, formalize a program for the interchange and common use of staff and students, develop a common training program, share facilities and equipment, use a common format for data collection, and establish a formal organization, central staff, and records file.

I. INTRODUCTION AND RECOMMENDATIONS

The Task Force on Organ Transplantation was announced on September 26, 1983 by the Secretary of Human Services and the Commissioner of Public Health, and charged with "the development of standards and processes for evaluating the use of organ transplantation" in Massachusetts. (See Appendix A) It was asked to

- make recommendations concerning how organ transplantation should be introduced and financed, including mechanisms to assure equality of access;
- determine what priority should be placed by the state on extreme and expensive medical interventions;
- determine what criteria should be used in patient selection; and
- determine how and by whom decisions concerning transplantation availability and patient selection criteria should be made.

The seventeen member Task Force is composed of citizens with personal or professional interest and expertise in organ transplantation including public officials, health care providers, representatives of major religious groups, insurance company officials, business leaders, and faculty members of local schools of public health. The Task Force held its first meeting in September, 1983 and has held fifteen meetings, including a public hearing, over a twelve month period. All meetings were open to the public, and there were no executive sessions. This report sets forth the final recommendations of the Task Force as well as a summary of the reasoning and facts on which these recommendations are based. Preliminary recommendations were announced by the Task Force in early

January, 1984, and these final recommendations clarify them, and add a section on the "consortium approach."

The Task Force has been well aware throughout its deliberations that its role in the public policy debate about organ transplantation is very circumscribed. The introduction of new medical technologies in the United States tends to take on a life of its own, and the impact of government policy on its diffusion has been very limited. Nevertheless, experience with kidney dialysis and transplantation has taught us that failure to plan can lead to tremendous unanticipated public expenditures and resource allocation problems. The Task Force has reviewed the kidney transplant history for the lessons it holds for the two procedures the Task Force decided to concentrate on: liver and heart transplantation. These are not only the ones currently clamoring for wider introduction into the system, but also provide useful policy models for decisions regarding other extreme and expensive procedures.

During the year the Task Force has worked, the transplant environment has continued to evolve. There were a series of Congressional hearings concentrating on organ procurement, sales, and federal financing, and the National Organ Transplant Act made its way through Congress. The Surgeon General continued his initiative to involve the private sector in organ procurement. In Massachusetts, four hospitals were granted certificates of need to do liver transplants under a "consortium" arrangement (see Appendix B) and, based in part on the recommendation of this Task Force, a single hospital was given a temporary exemption from DON to do cardiac

transplantation (see Appendix C). Massachusetts Blue Cross/Blue Shield initiated a "Transplant Insurance Program" (TIP) for its group subscribers, and in early 1984 decided to include organ transplants as part of its basic coverage. Massachusetts Medicaid also pledged to cover necessary heart and liver transplants. A statute was enacted in Massachusetts in late December 1983 to set up a separate fund, financed by donations and contributions made from state income tax refunds, to help pay for organ transplants for those unable to finance them themselves. This "checkoff" system will begin in 1985.

Why all this interest in organ transplantation, and why a Task Force to examine "the difficult ethical and financial decisions" involved? There is no single reason, but the following combination of factors together appear to account for the current focus on liver and heart transplantation:

- those needing them are easily identified, need them quickly to survive, and have often been able to get their plight highly publicized;
- transplants are viewed by the public as life-saving;
- the transplant procedure is extremely expensive, so that its general provision may have a significant impact on the health care system, and this is the first time rationing such a procedure has been seriously discussed by public officials; and
- denial of a transplant on the basis of inability to pay seems to unfairly restrict the procedure to the wealthy, and seems to place a specific price on life.

The issue has also taken on special importance in Massachusetts for at least four reasons: (1) Massachusetts has been blessed with some of the most outstanding hospitals and medical schools in the country and has always been seen as a major medical research center; (2) the first kidney transplant and the second series of liver transplants were done in Massachusetts; (3) the Trustees of the Massachusetts General Hospital explicitly decided not to engage in heart transplant surgery in 1980 because of the tremendous cost of a program which would benefit only a few patients (this unique step by a major hospital was not rescinded until 1984); and (4) Massachusetts is the home of Jamie Fiske, who received a liver transplant in Minnesota in October, 1982, and whose father, Charles Fiske, has done more than any single person to publicize the inadequacies of the present system of financing and obtaining a liver transplant.

Nonetheless, although the Task Force was asked to prepare a set of recommendations in a four month time period, the Task Force did not view this as a major policy emergency from the point of view of Massachusetts citizens as a whole. In 1983, for example, only 5 (4 liver and 1 heart) Massachusetts citizens had to leave the state to seek non-kidney organ transplantation; and only 8 procedures were done within the state. The individuals involved could, of course, have been better served if public policy had been in place. But in such a new, expensive, complicated, and rapidly evolving field about which little is known concerning the need, outcome, quality control requirements, or cost of procedures, these problems are inevitable. The Task Force decided it was prudent to examine them critically and

carefully rather than rushing to conclusions that might, in the long run, cause more suffering and problems than they prevent.

On the federal level, almost exclusive energy is being devoted to increasing the supply to transplantable organs by making the organ procurement system more efficient. In Massachusetts and New England, organ procurement problems are real, but this has not been the primary factor limiting use of this technology, and witnesses before the Task Force indicated that it is not likely to be the major issue in the forseeable future for our region. Accordingly, exclusive concentration on organ-procurement is at least premature. The reason for this region's position in organ procurement is the success of the New England Organ Bank, and their work deserves wider public attention and support.

The major public policy issue in organ transplantation is how to move toward three goals simultaneously: quality of services, equality of access to services, and cost-containment. Even assuming that we can maintain the high quality of care offered to Massachusetts citizens, will it be possible to simultaneously increase equity of access to services, and decrease or limit its cost? Assuming a limit on total health care and medical expenditures, some trade-offs must be made. In a country in which organs for transplant are routinely sought from other states, and in which citizens may freely travel to seek medical assistance, a national approach to organ transplants is both desirable and necessary. No individual state can develop an effective organ transplant program without utilizing a multistate organ procurement network. Nor can any state act as an organ

transplant center without reasonable reimbursement policies in place in the states from which it draws its patients. Nonetheless, in the absence of any federal leadership in the area of organ transplantation, it would be equally irresponsible for the individual states to do nothing. Even though we cannot do as well as we would like, we should do as well as we can.

Ultimately, of course, one would like to eliminate the need for organ transplantation. It is a powerful and often life-saving technique, but while it may circumvent the patient's underlying illness by replacing a diseased organ with a non-diseased organ, it gives the patient a new life-long problem: coping with immunosuppression to prevent organ rejection. The Task Force's mandate did not include making recommendations on basic science research or the comparative value of preventive programs (including public health programs to encourage exercise and reduce weight, smoking and alcohol consumption). Nonetheless, the Task Force believes that efforts in both basic science research and preventive approaches should be vigorously encouraged as the long term approach to major organ failure.

We are under no illusions that these recomendations are the "final word." Our hope is that this is a helpful report and that other states and those working toward a coherent national policy will find it constructive.

FINDINGS AND RECOMMENDATIONS

The Task Force finds that the primary values at stake in organ

transplantation are human life, equity, and fairness. Organ transplants are extremely expensive; the fully-allocated average-one-year-cost is $230-340,000 for liver transplants and $170-200,000 for heart transplants. This is in the range of 4-10 times the cost of the other most expensive currently-employed medical technologies (See Section III). Nonetheless, the Task Force believes that these procedures should be performed on those who are likely to benefit from them, so long as the total cost is controlled, and resources are not diverted from higher priority medical procedures to liver and heart transplantation. The question of what a "higher priority" procedure is will be based on the total number of individuals affected, and the importance to their lives of the intervention. For example, it may be appropriate to shut down an underutilized maternity program to do organ transplants. The burden of demonstrating that such a tradeoff is appropriate, however, should be on the hospital proposing it. Accordingly, in the determination of need (DON) process, all currently available health care services should be presumed to be higher priority than transplantation. The applicant should have the burden of demonstrating that transplantation has a higher priority than any other currently available health care service from which organ transplantation diverts funds and/or support systems.

On the issues of equity and fairness, we concur with the conclusions of the President's Commission for the Study of Ethical Problems in Medicine: society has an ethical obligation to ensure equitable access to health care for all; and the cost of achieving

equitable access to health care ought to be shared fairly.* Transplantation of livers and hearts should therefore only be permitted if access to this technology can be made independent of the individual's ability to pay for it, and if transplantation itself does not adversely affect the provision of other higher priority health care services to the public. We believe it is possible to achieve this goal only by the gradual introduction of this technology in the Commonwealth, a close and careful monitoring of quality care, costs, outcomes, and patient selection, and provided that liver and heart transplantation can be done in the Commonwealth in a manner that does not necessitate additional capital expenditures for this purpose. The existence of Ch. 372, the DON procedure, and rate setting, give us some confidence that this is possible.

Recommendation 1

Liver and heart transplantation should be introduced into the Commonwealth in a controlled, phased manner that provides the opportunity for effective evaluation and review of its clinical, social, and economic aspects by a publicly-accountable body after an initial phase of 2-3 years of limited transplantation.

Discussion

The Task Force's basis conclusion is that heart and liver transplantation should be introduced into the Commonwealth of Massachusetts, but that the introduction should be done in a

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*President's Commission for the Study of Ethical Problems in Medicine and Behavioral Research, SECURING ACCESS TO HEALTH CARE, Vol. One, 1983, at 5.

deliberate and cautious manner through a carefully monitored, phased approach. The findings and recommendations of the Task Force concentrate primarily on "Phase I", which may be termed the phase of "Initial Social Assessment." During this phase a limited number of heart and liver transplants should be performed in an atmosphere that maximizes the potential for clinical, economic and social data gathering. The anticipation is that sufficient data will be gathered during this 2-3 year phase to provide the basis for a decision by the Public Health Council and other publicly-accountable bodies to determine the direction and scale of the next phase.

Recommendation 2

The decision of when extreme and expensive medical technologies, like heart and liver transplantation, should be generally available should be made only after the clinical, social, and economic consequences of introducing the procedure, including cost-effectiveness, ethical implications, and long term effects on society, are studied and reviewed by a publicly-accountable body.

Discussion

Tests currently used to determine when a new procedure should be generally available, like experimental vs. therapeutic or pretherapeutic, or "safe and effective", tend to concentrate the discussion on the technical aspects of a new procedure without consideration of its impact on society in terms of values, financing, skewing the system, or allocating resources. Whatever the

appropriateness of such tests in the past, these technical-assessment-based tests cannot serve as a reasonable or useful threshold test for the general introduction of extreme and expensive procedures in an era of resource constraint. Bodies like the Task Force can act as appropriate forums for examining the "social consequences" involved in introducing new medical technologies into the system, and making recommendations to publicly-accountable agencies like the Public Health Council.

The decision on whether particular, extreme and expensive procedures should be generally reimbursed should be made in such a way that Medicaid does not become the de facto insurer for all such procedures. One possible mechanism would be a joint committee with representation from the state and the insurance companies, with input by external evaluation groups like the Task Force and federal agencies like the U.S. Office of Technology Assessment. Using this or some other analogous mechanism could help ensure fairness in the distribution of burdens regarding reimbursement.

Recommendation 3

In making a decisions regarding an application for a determination of need (DON) for heart and liver transplantation, the Public Health Council should attempt to minimize and track the total incremental cost of adding these procedures to the health care system.

Discussion

Although the Task Force endorses the limited and controlled

introduction of organ transplantation in Massachusetts, it does so only because it believes that it can be done without decreasing services in other medical sectors, and that the total demand can be met without additional capital expenditures. Whether or not this assumption is correct, of course, remains to be seen. Testing this view will require careful monitoring of the impact of organ transplantation performed at major university facilities on such things as ICU utilization in community hospitals, as well as on the general case mixes in the hospitals. While it might optimistically be hoped that both heart and liver transplantation can be introduced in Massachusetts without capital expansion by increased efficiency and "taking up the slack in the system", it is uncertain what the "spill over" effects will be and how many (if any) more similar technologies can be "painlessly" introduced in the future. As a principle, the Task Force believes that if it turns out that liver and heart transplantation take resources away from higher priority health care services, and decrease their accessibility to the public, these transplantation procedures should not be performed.

To help evaluate the effects of organ transplantation on the system, as well as its cost and quality control mechanisms, and monitor Phase I, the Commonwealth of Massachusetts should contract with an independent evaluation group with medical and economic expertise to collect and analyze data on liver and heart transplantation during Phase I.

Current information about the need for, costs of, and outcomes of liver and heart transplantation is insufficient to justify any more

than the very limited and controlled introduction of these technologies in Massachusetts. For example, the "additional evidence about the effectiveness and safety" of liver transplants anticipated by the Fineberg Report has not yet materialized. An independent evaluation group could collect and analyze comprehensive data during Phase I, and present it to the Public Health Council in a credible manner, as an essential aid in their decision making process. For further discussion, see section III.

Recommendation 4

Until such time as there is reasonably reliable data on the need for, costs of, and outcomes of liver and heart transplantation (end of Phase I) hospitals proposing to do these procedures in the Commonwealth should not be given a certificate of need unless they agree to (1) support the operating expenses for heart and liver transplantation within current reimbursement limits set by the hospital's maximum allowable cost under Ch. 372 of the Acts of 1982;* (2) collect evaluative data on the costs, outcomes, and displacements caused by transplant candidates who receive transplants as well as those who do not, in a manner approved by the Department of Public Health, and agree to make this data available to the Department and an independent evaluation group; and (3) have its protocols reviewed, approved and monitored by its Institutional Review Board (IRB), or by a special review board set up for this purpose by the Department of Public Health.

*provided that an exception may be granted for expenditures that are unique to organ transplantation: the cost of the organ itself and the cost of the Cyclosporin A.

Discussion

Implicit in this recommendation is the Task Force's view that the determination of need process is an appropriate one for required review and prior approval of this extreme and expensive technology because of the major impact it is likely to have on the health care system. The requirement of working under the "MAC" or maximum allowable costs echoes the Fineberg Task Force recommendation which it believed should hold until "the representative advisory body [this Task Force] has rendered a judgment about adding costs to the health care system for such extreme and expensive procedures." **As previously noted, the factual data upon which such a judgment can be rendered is not yet available.

Finally, subparts (2) and (3) of this recommendation recognize the need to collect data in a systematic and complete manner, and recognize that whether it is characterized as experimental, pre-therapeutic, therapeutic or by some other designation, both heart and liver transplantation require and demand significant research and data collection activities that make IRB review or analogous protocol review by a similarly-constituted body both warranted and useful. Special attention in this review should be focused on the consent procedure utilized by the institution, procedures used to withdraw consent and order the withholding of future treatment (if and when

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**Final Report of the Task Force on Liver Transplantation in Massachusetts (The "Fineberg Report"), May 1983 at 40.

patient determines he or she does not want further treatment, even if such a decision will result in death), organ procurement procedures, patient selection procedures, and issues of confidentiality.

Recommendation 5

Patient selection criteria should be public, fair, and equitable. Primary screening should be based on medical suitability criteria made available to the public which is designed to offer transplantation to those who can benefit the most from it in terms of probability of living for a significant period of time with a reasonable prospect for rehabilitation. If there are insufficient resources to transplant all who can so benefit, selection from the medically-suitable group should be based primarily on a first-come, first-served basis. The selection criteria and process should be filed with a publicly-accountable body.

Discussion

Fairness and equity demand that no one be excluded from the pool of potential recipients because of social class, ability to pay, family situation, or place of residence in New England. Referral patterns need to be examined, but all candidates who are referred for transplant should undergo the same medical screening examination. In this screening examination, age can be taken into account as one factor (insofar as it may affect longevity and prospects for rehabilitation), but cannot be used alone as an arbitrary disqualification. Likewise, the policy should recognize that

Massachusetts has a special, historical relationship to our neighboring states, and that residents of the New England states that have been involved with the New England Organ Bank's program should be eligible for transplants on the same basis as Massachusetts citizens. Their state of residence should adopt mechanisms to reimburse Massachusetts hospitals for their transplants.

For liver transplants especially, active alcoholism may be taken into account insofar as it might affect the longevity and prospects for functional rehabilitation, but not as an absolute contraindication. As the President's Commission has properly noted:

> In light of the special importance of health care, the largely undeserved character of differences in health status, and the uneven distribution and unpredictability of health care needs, society has a moral obligation to ensure adequate care for all.*

Similarly, although family support networks may be extremely important in after-hospital care, the absence of a family or the existence of an uncoventional substitute should not serve as a reason to exclude the patient from evaluation. Society should develop mechanisms, in cooperation with the transplanting hospitals, to provide sufficient support resources for such patients during their recuperation. The cost of after care, including visiting nurses or other needed medical support for a transplant candidate without a family or other social support, should be included in the analysis of the cost of the transplant procedure itself. Hospitals should develop

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*President's Commission for the Study of Ethical Problems in Medicine and Behavioral Research, SECURING ACCESS TO HEALTH CARE, Vol, One, 1983, at 25.

plans for dealing with such patients, and these plans should be included in their DON applications.

If the pool of medically-acceptable candidates is larger than available resources, patient selection should be made on a first-come, first-served basis with consideration of the donor organ "match". This is expected to be close to a random allocation, and is probably the fairest we can do at this time. Individual adjustments in the system may be called for in a medical emergency, or where some on the waiting list are from outside New England. New England residents can be given preference so long as this policy is made known to non-New England residents before they are medically evaluated for transplant; and during Phase I, non-New England residents should not be screened unless they have demonstrated an ability to finance their transplant.

In the event that an individual believes he or she has been discriminated against unfairly in the selection process, the hospital should have an appeals mechanism in place to enable the individual to present his case promptly and fairly to a neutral decision-maker with authority to have the patient's case reviewed again by the selection team. For further discussion, see section IV.

Recommendation 6

If more than one hospital is granted a certificate of need to do heart or liver transplantation, all hospitals so involved should be required to coordinate services in a way that comes as close as possible to a single, integrated medical service. Each hospital should be able independently to demonstrate either its ability to

perform the procedure, or to act in concert with the other hospitals in a particular aspect of the procedure. All hospitals should establish and use a single set of patient selection and treatment protocols, agree to joint publication of research results, use a common patient recipient pool and a common organ procurement pool, formalize a program for the interchange and common use of staff and students, develop a common training program, share facilities and equipment, use a common format for data collection, and establish a formal organization, central staff and records file.

Discussion

In general it seems best to inaugurate extreme and expensive medical technologies like heart and liver transplantation either at a single facility or at a "consortium" that meets the criteria set forth in this report. This is consistent with recommendation 1, that liver and heart transplantation be introduced into the Commonwealth in a "controlled, phased manner." Looked at purely from an economic point of view, one cannot make out a case for initiating organ transplantation at more than one hospital. Nonetheless, truly cooperative efforts have some other potential advantages. In the case of liver transplantation, the Public Health Council has already granted certificates of need to four individual hospitals who have agreed in principle to work together. (Appendix B) On the other hand, an exemption from DON for heart transplantation has been granted to a single hospital for a limited period of time. (Appendix C)

As a result of the debate regarding the "consortium" approach to

liver and heart transplantation, the Task Force has developed guidelines for a "worthwhile" consortium, consistent with our other basic recommendations. In order to prevent duplication, minimize new capital expenditures, prevent the displacement of significant numbers of patients, and help assure high quality care, we believe a formal cooperative agreement among all the hospitals involved in a consortium should be required by the Public Health Council. This agreement should insure that the multiple-hospital consortium arrangement is truly cooperative, and is run like a single, integrated medical service.

Each applicant must, of course, independently demonstrate its clinical ability, and the necessity of its involvement in transplantation from the public's perspective. A single set of patient selection and treatment protocols must be agreed upon and used, as well as a single set of data collection criteria and an agreement to joint publication of all research, so that there will be a sound basis on which to make policy judgments after "phase one." To help formalize cooperation and maximize the utility of a group effort, written agreements regarding the interchange and common use of staff and students should be entered into, as well as agreement regarding the development of a common training program, and efficient joint use of facilities and equipment. To coordinate all of this, and maintain records on it, a formal organization with a central staff and record file will be required. For further discussion, see section V.

II. THE STATE OF THE ART

The first successful transplantation of a vascularized whole kidney under immunosuppressive chemotherapy was carried out in Boston in March, 1962. This transplant was the culmination of studies and experience spanning a decade of intensive work in the field. Since that time remarkable progress has taken kidney transplantation from the realm of experimental surgery to a viable approach for the treatment of end stage renal (kidney) failure. While scientific and technical problems were being overcome, many social and ethical issues were raised. The medical community could not as easily address the political, economic and logistic questions created by this new technology.

This section contains a brief survey of the current status of organ transplantation as it pertains to the work of the Task Force. The emphasis is on experience with kidney transplantation, the development, current volume and outcomes of liver and heart transplantation, and on the development of organ banking. Our intent is to present a broad overview of transplantation for the general reader. This precludes an exhaustive review of the most current literature, which reflects changes reported each month.

Discussion of any type of transplant must address the goals of this treatment modality. It is often assumed that a transplant cures a patient of disease. This is simply not true. For instance, atherosclerosis (hardening of the arteries), the major cause of heart disease and death, is not eliminated when a new heart is transplanted. The disease process of narrowing of the blood vessels continues, even in the transplanted heart. With every transplant, the body also has

the burden of a foreign tissue (the new organ) with which to contend, and immunosuppressive drugs must be taken for the remainder of the patient's life to prevent rejection. Transplantation can improve life both in quantity and quality, but it rarely returns a patient to fully normal health. The primary goal of modern medical research remains that of understanding the cause, and prevention, of diseases so that eventually the need for transplant, and many other temporizing measures, will be eliminated. Until such time many technically complex procedures offer an improved quality of life for many patients.

Transplantation of the Kidney

Since the first transplant in 1962, it is estimated that more than 100,000 kidney transplants have been performed throughout the world. Publications in the medical literature concerning transplantation continue to grow rapidly, and today approximately 3,000 medical articles appear annually on the subject.

In 1982, more than 5,300 kidney transplants were performed in the United States. At present, nine hospitals in New England, seven of them in Massachusetts, each perform from 10 to 57 procedures each year. The total number of procedures performed in New England has steadily increased from 193 in 1978 and 257 in 1982, to an all-time high of 313 in 1983[1] (including 19 pediatric patients), with kidneys harvested from both cadavers and living-related donors.

As increasing numbers of transplants have been performed, survival rates of both the patient and the kidney graft have improved. In a

recent study,[2] 86 percent of recipients of kidneys from unrelated donors survived one year, and 78 percent survived to three years. Of those receiving kidneys from related donors, 95 percent survived to one year and 91 percent to three years. The reason that overall survival is better for people who have related donors is because there is less chance for kidney rejection. Kidney graft rejection exacts a huge toll on the patient with increased stress, higher likelihood of infection and a consequential higher mortality. Return to dialysis and the possibility of a second graft remain an option. Graft retention rates have been lower than patient survival rates, and removal of rejected kidneys in cases where the graft is not successful has resulted in greatly reduced patient mortality. Retention rates for transplants from unrelated donors are 56 percent for one year and 45 percent for three years, while 75 percent of organs from related donors have been retained for one year, and 67 percent for three years. Due to improved immunosuppression, graft retention rates have shown progressive and substantial increases. Patient survival rates improved drastically, and have recently remained stable.[3]

Kidney disease differs from other terminal, organ-specific diseases in two important ways. Since human beings possess two kidneys, and can live comfortably with one, it is possible to obtain a healthy, well-matched kidney from a donor (living or recently deceased). Secondly, and more importantly, dialysis is available as an alternative life-sustaining measure to assume the functions of the diseased kidney either on a long term basis or while the patient awaits a transplant. In addition, patients from whom a rejected kidney

is removed are able to return to dialysis. In 1983, of the 69,409 patients on dialysis in the United States, 2,399 were in the New England area. Less than half of these patients are considered potential candidates for a transplant and only about 6,000 are on a formal waiting list. Being a candidate is a function of organ availability, patient selection criteria, and patient preference.

Treatment selection for patients with kidney failure is a choice between dialysis and transplantation. If a patient suffers severe concomitant disease (e.g. widespread cancer, emphysema or liver failure) that will not be improved by receiving a transplanted kidney, the patient will be a dialysis candidate. If the patient has a disease, such as high blood pressure or diabetic retinopathy, which is likely to be improved by transplantation, then the patient will preferably be selected for transplantation. Another factor favoring transplantation is availability of a suitably-matched, living-related donor. The patient's own wishes are paramount in any decision to seek transplantation.

The transplant team itself is, of course, critical. There is an important skill and experience factor in successful performance of any complex medical team effort. Transplants seem to function best when supervised by a well-balanced professional group in a medical center. Ideally, transplantation should involve physicians and surgeons possessing a variety of skills and backgrounds and a hospital with services broad enough to carry the added burdens of blood banking, chemical treatments that are sometimes toxic, treatment of severe disease in other organ systems, and rejection. A well-balanced

professional group in the field of kidney transplantation involves many skills including medical nephrology, cardiology, bacteriology, immunology, surgery, vascular surgery, urology, social services, psychiatry, and teams experienced in troubleshooting both dialysis and transplantation. Even though it seems intuitively correct that medical centers with a larger number of patients, hence more experience, would be more successful in transplantation, some small groups have done well on measures of mortality and morbidity. Unfortunately, other small groups have produced results which are not as encouraging. At present, factors such as experience and professional balance must be weighed in determining the liklihood of a favorable outcome.

Throughout this report, kidney transplantation is discussed as a useful benchmark because it is established. Now the foundations for transplantation of heart, liver, and other organs must be established. The experiences with kidneys, and the lessons learned in the procurement of organs, patient selection, reimbursement, and broad social policy are often applicable to other organ transplants. For example, kidney transplantation has brought into sharp focus questions concerning public financing of costly high technology procedures. Moreover, increasing acceptance of the procedure by clinicians has coincided with greater public awareness of the availability of these procedures, and a willingness to participate in organ donor programs to utilize organs that would otherwise be lost in the unfortunate deaths of family members. The experience with kidney transplantation has demonstrated the importance of having social, financial, and ethical factors considered, debated, and, if possible, resolved, simultaneously with the development of medical techniques.

Transplantation of the Heart

Since 1967, approximately 900 heart transplants have been performed worldwide, 635 of those in the United States.[4] World experience in heart transplantation has been dominated by the work of Dr. Norman Shumway at Stanford University Medical Center, Palo Alto, California. Heart transplants performed on dogs by Dr. Shumway in 1958 anticipated the first human heart transplant in 1967 by Dr. Christiaan Barnard in South Africa. Within a year, about 100 heart transplants were performed worldwide, but with dismal survival rates.[5]

Data for survival of heart transplant patients at Stanford University was collected in four distinct temporal phases. First came a period when potential transplant patients were identified. Shumway found candidates for the operation, but a transplant was not performed. Ninety percent died within two months, and all died within nine months. Second, came the period between January, 1968 and December, 1973, in which there was an initial 45 percent survival rate. The remaining 55% of patients were lost in the operative or early hospital period. Survivorship subsequently declined to 25 percent at five years. In the third phase, January 1974 through December, 1980, initial survival rates improved to 62 percent at one year, and 45 percent at five years. In the fourth and most recent phase, December, 1980 through May, 1983, survival rates improved to 82 percent at one year, and 78 percent at two years, with estimates of 65 percent at five years.[6]

The fairly dramatic improvement in survival rates appears to be

the result of at least three medical factors: improved clinical and operative management, improved immunosuppression, including the introduction of a new and seemingly more effective drug, Cyclosporin A, and improved patient selection. No one factor can be isolated as the most important reason for increased survival rates.

An enhanced outlook for both survival and a return to normal life appears to have added momentum to interest in transplantation: the 172 heart transplants performed in the United States in 1983 represent nearly one third of the total heart transplant operations since 1967. These transplants were performed at eleven transplant centers throughout the nation. Worldwide, heart transplant operations are conducted in Canada, Great Britian, France, and South Africa. Of the 635 United States heart transplants, 295, or 46%, are still living. The current total one year survival rate is 80% and a two year survival rate of 75% is projected.[7] One year survival has gone from 44% in 1973 to 88% in 1983. Presently the leading causes of death are infection, acute rejection, graft arteriosclerosis, and malignancy.[8]

Estimates of potential annual need are extremely variable and range from 1,000 to 75,000 nationwide, and from 20 to 1,800 in Massachusetts. Conditions which may necessitate heart transplantation include intractable heart failure of several causes, coronary obstructive disease, cardiomyopathy and, in young people, congenital heart disease and tumors. The larger national estimate assumes that one out of every four patients less than 50 years of age and dying of cardiac disease might be a candidate for cardiac transplantation.[9] The smaller national estimate is based on a series of selection

criteria and contraindiations to transplantation developed at Stanford University.[10] For Massachusetts, the larger estimate is simply a proportionate share of the national figure based on population. A more conservative figure of 109 operations annually was arrived at by applying more rigid criteria: limiting patient age to 15-49, eliminating those with kidney disease or diabetes, and subtracting the one third who unfortunately might be expected to die while awaiting a transplant. The estimate of about 20 was put forth to the Task Force by the three hospitals in Massachusetts proposing to do heart transplantation in May, 1984. The great variability in these estimates leads to a conclusion that we simply don't know what either the "demand" or "need" for heart transplants is likely to be with any degree of certainty.

Transplantation of the Heart and Lungs

The transplantation of heart and lungs is still in its nascent stage. It remains in the realm of such experimental procedures as the artificial heart and pancreatic transplant. Initial exploration of the double transplant (heart and lungs) is encouraging, but the procedure has not yet been employed on a scale large enough to provide mortality parameters similar to the worldwide experience with kidneys, hearts, and livers.

Approximately 23 heart/lung transplants have been performed, including 17 at Stanford University under the direction of Dr. Shumway. Other centers performing the procedure are the University of

Pittsburgh and Johns Hopkins University. Of the 17 transplants performed at Stanford, 11 patients are alive including the first patient transplanted in March, 1981.[11]

Patients needing a heart/lung transplant suffer either from pulmonary hypertension or Eisenmenger's Syndrome. These two conditions are unusual diseases of varied etiology which have in common concomitant disease of heart and lungs. No single replacement of either heart or lungs ameliorates these conditions and at present no other mode of treatment has met with success. Both pulmonary hypertension and Eisenmenger syndrome are relatively rare but serious illnesses with a high mortality. Successful transplantation of the heart and lungs together involves identical determinants of success (immunosuppression, team experience and balance, specialized clinical knowledge) that characterize all other organs.

Transplantation of the Liver

Initial experimental whole organ transplantation of the liver by the method now used in patients was reported from Boston in 1959;[12] four clinical liver transplants were conducted in Boston in 1963-1965 without success. Since that time, the major work in this field has been conducted by Dr. Roy Calne at Cambridge University, England, and Dr. Thomas Starzl, formerly of Denver, Colorado, now in Pittsburgh, Pennsylvania.

Recently tabulated results by Calne[13] from four centers cover 466 liver transplants in 434 patients from 1963 to 1982. Of these, 163

are now alive, while 36 died within six months. A total of 123 (28%) are living three years or more after the transplant. Dr. Starzl has prepared actuarial curves contrasting the data from his Denver-Pittsburgh centers for 1963-79 with that from 1980-82. One year survival has increased from approximately 30% prior to 1979[14] to approximately 60% in the 1980-1982.[15]

Projections of the need for liver transplants in Massachusetts are based on estimates of the prevalence of certain liver diseases. About 90 percent of all deaths from liver disease in Massachusetts are a result of cirrhosis (alcoholic and post-hepatitic) and hepatitis. Important minor causes are primary biliary cirrhosis and biliary atresia. Dr. Starzl estimates the potential need for liver transplantation to be approximately 20 per million population or 114 patients in Massachusetts and 246 in New England, although based on actual experience in Massachusetts, these estimates seem high.

A unique feature of liver transplantation is the presence of two distinct patient populations in need of transplant. Adults, who have several causes of liver failure (e.g. hepatitis and alcoholic cirrhosis) and various underlying diseases (e.g. coronary artery disease, emphysema) and children, of whom 90% of those suffering liver failure have a congenital disease called extrahepatic biliary atresia (a disease affecting the secretion of bile). The problems that face these groups are very different, and these distinct patient populations are often evaluated separately. A group may be prepared to do liver transplants in children based on their own experience as a childrens' hospital or based on prognostic, ethical or technical considerations.

The same group may not be prepared to do liver transplantation in adults. A second clinical center may decide just the opposite. Projections for liver transplantation in children are based on several data sets. Extrahepatic biliary atresia has an incidence of one in 8,000 to 10,000 live births. About 30 percent of these cases will be aided by other surgical procedures and will not require an early transplant. On the basis of existing data, seven Massachusetts children annually could be expected to have biliary atresia requiring a transplant.

Issues in Immunosuppression

One of the major problems inherent in organ transplantation is rejection of the grafted organ by the recipient's immune system. To control rejection, drugs which suppress the immune system are administered post-operatively. Since its introduction in Boston in 1961, Azathioprine (Imuran) has been the standard drug, often used with cortisone. Now, cyclosporin offers promise of improvement. Cyclosporin A is produced by the Sandoz Corporation, in Basel, Switzerland, and marketed under the name Sandimmune. Though many have attributed the increased survival of transplant patients to cyclosporin, it is premature to give it full credit. The drug has been in use in the U.S. for a limited period of time and the most current data [16] reveal more profound toxicity than previously appreciated. Considering the limited data, apparent toxicity, and a cost of $6000 per year, the drug should not be used as the sole or major impetus for

encouraging expanded transplantation volume. More credit should be given to the growing experience, better surgical technique, better patient selection, and better postoperative management and immunosuppressive regimens. Further research and time is needed to evaluate more fully the role of cyclosporin in transplant immunosuppression. The potential benefits of using cyclosporin are exciting, but enthusiasm must be tempered until more information is available.

Organ Procurement and Banking: Coordination and Regionalization

Organ transplantation is unique in that it involves two human beings in a technology-mediated exchange of live organs: one human (alive or dead) donates an organ to a diseased recipient. Living kidney donors (either related or unrelated) were initially used because kidneys are paired organs. Even at the very outset of the kidney program, however, it was clear that cadaver tissues would also be used and that timing, preservation, and transportation of organs would be central to success. For livers, hearts, and heart-lungs, all donors must be deceased persons who meet brain death criteria and whose respiration is mechanically maintained; in many instances postmortem survival of other organs is assured by temporary pump-oxygenation support of the circulation.

With the growing need for fresh and viable organs, it became apparent that kidney transplants could be managed best on a regional basis with a central clearing house of clinical information on donors

and recipients. The New England Organ Bank was one of the first regional organ banks established, and today transplant patients in Boston receive organs from as far away as the Midwest and Southeast. Moreover, the various regional banks in the country trade organs extensively according to supply and demand: a recent study showed that transplantations conducted in Richmond, Virginia used organs harvested as far away as Massachusetts and Texas. An expanded regional organ banking system would have to be an integral part of any initiatives taken in Massachusetts for the transplantation of livers, hearts, or hearts and lungs.

Successful organ banking requires cooperation at five levels of public and professional activity: public education, hospital preparedness, surgical training, organ preservation and transportation, and centralized coordinating and dispatching.

A central coordinating organization must possess a list of potential organ recipients and maintain communication with regional hospitals in the event an organ becomes available. In addition to data assembly and information dispersal a central organization has the responsibility of acting within the time restraints that perishable organs require.

The New England Organ Bank serves as a role model. It is rapidly expanding its tissue procurement programs, and continues to build public support that will benefit additional transplant programs. The New England Organ Bank, however, cannot function without adequate support from all agencies; fiscal support of its work must be considered an integral part of the cost of tissue transplantation.

Public Education

Media attention given to several recent transplant patients has heightened public awareness of the procedure, and a new level of awareness was reached in the spring of 1984 with the proclamation by President Ronald Reagan of National Organ Donation Awareness Week, April 22-28. With activities such as this, the possibility of donating or bequeathing organs is gaining public acceptance. Even though laws in all states permit individuals to sign a donor card, very few doctors and hospitals will use the organs of such a person without the added consent of the next of kin. A vigorous campaign to educate the public and health professionals including doctors, hospital personnel, medical examiners and coroners, would be extremely helpful. The media could educate by indicating to the public the need for their cooperation and the benefits to society of active participation. The airing of documentaries and public service announcements would probably best achieve these goals rather than the publicizing of dramatic isolated cases. In several instances the families of recently deceased teenage children have been the prime movers in making those precious organs available to others; they have found some solace, in their grief, to helping others. The public, through the media, is most receptive to such knowledge, and is educated thereby; but careful steps should be taken to guard the confidentiality of patient information and maintain the anonymity of donors.

Hospital Preparedness

Tissue destined for transplant must be obtained by an experienced physician. Respiration is generally maintained mechanically, and is continued after death to permit the organs to survive. As many as eight tissues or organs may be harvested: eyes, skin, bones, heart, kidneys, liver, and lungs. To maximize the value of these scarce resources, hospitals involved in the chain of donation require trained personnel, sophisticated equipment, communication systems, and cooling devices.

Surgeon Training

The surgical procedure for harvesting kidneys is fairly simple. In New England surgeons cooperating with the Organ Bank have obtained expertise at removing kidneys. In the case of livers and hearts, a surgeon from the hospital where the recipient is being cared for will most likely be dispatched to remove the tissue from the donor and supervise its return. Such capability and preparedness requires special training, communication networks and transportation systems.

Preservation and Transportation

"The faster, the colder, the better," best describes the goal of teams that carry living organs from one hospital to another. Properly handled and attached to a special oxygenating device, a kidney can

remain viable for 72-96 hours after harvest; presently, hearts and livers perish after 12 hours. The excitement and urgency of the transportation of a liver or heart makes for a dramatic newsworthy event. The media often covers these stories, which can help in public education as already mentioned.

Considerations of Brain Death

In the area of death, the law has always been and remains that an individual is dead when a licensed physician pronounces him dead, so long as the physician makes the determination based on "accepted medical standards."[17] Brain death has been an "accepted medical standard" for more than a decade, and every court that has examined the question, including the Massachusetts Supreme Judicial Court, has agreed that brain death is a legally proper determination for a physician to make whether or not there is a state statute on the subject.[18] Where physicians are unclear about this, education is indicated.

Uniform legislation does not, however, overcome deeply held convictions or conventions. For example, although the Uniform Anatomical Gift Act, which is law in all 50 states, makes a person's donation of an organ by use of a donor card effective upon declaration of death, almost no physician or hospital will in fact use the person's organ without permission of the next of kin. This permission is not legally required, but appears to be sought for personal, psychological and perhaps public relations reasons. The presence of the donor card,

however, probably does make the relatives more likely to agree to the donation.

Sales

One of the most bizarre proposals to increase the supply of kidneys has been to develop a "kidney exchange" which would put willing sellers in touch with willing buyers. This proposal has occasioned an outcry from those who believe it will exploit the poor, bring commercialism into the transplantation field, and decrease the supply of donated organs. The Congress and a number of state legislatures are currently considering legislation to outlaw such sales, although there have as yet been no reports of actual sales having taken place in the U.S., and the position of the transplant surgeons is that they will not transplant an organ which has been privately paid for. Since we do permit the poor to take all sorts of occupation risks with their bodies, it does seem somewhat paternalistic not to permit them to take this one. Nonetheless, this is a highly visible and symbolic exploitation, and one that has the potential to undermine society's belief in the integrity of the entire transplantation enterprise.[19] Therefore it seems reasonable to the Task force to strongly oppose organ sales, and if a credible attempt to establish a sales network ever develops, state laws directly outlawing such sales would be appropriate.

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III. THE ECONOMICS OF ORGAN TRANSPLANTS

I. The Role of Quantitative Analysis in Setting Policy on Organ Transplants

There has been a great deal of recent attention to the use of formal quantitative analysis in public policy decisions. The purpose of this section is to explore the possible role of such techniques in the work of the Task Force.

In approaching this question, we must realize that no analytic technique can be any more persuasive or compelling than the assumptions on which it is based. Every method has built into it certain ethical biases. There is no purely "scientific" way to decide what "ought" to be done in any given situation. In addition, describing the consequences of alternative policies in numerical terms has both advantages and drawbacks. Making our prediction quantitative forces us to be explicit and precise in our thinking. On the other hand, there may be no practical index or readily available number that does a good job of measuring what we really care about. And it is all too easy, as an analysis progresses, to ignore that which is not measured. Hence, formal analysis can distort as well as sharpen, thus obscuring rather than clarifying the central issue.

Historically there have been two main approaches to policy analysis, although these two schools have increasingly come together in recent years. One has its roots in economics and economic efficiency. The key ethical assumption is that the purpose of all economic activity (including health care) is to satisfy consumer preferences. An efficient activity is one where consumers

(or beneficiaries) would pay more for it than the costs of production. This follows because, in a competitive economy, the price a producer has to pay for any input will equal the market value of the output that input could produce elsewhere. The various buyers of any input will bid up its price until the cost of that input to them is equal to what they could gain by utilizing it. Now suppose that the buyers or users of some good or service would pay more for it than it costs. That must mean that the good or service in question will produce more consumer satisfaction than the outputs which its inputs might otherwise produce. Thus if, and only if, consumers are willing to pay more than the costs of producing what they consume, is it efficient to provide them with that output. This is the test that cost-benefit analysis uses to judge public policy.

For several reasons the Task Force believes that this approach is unlikely to be helpful to its decision making. First, any individual's willingness to pay is limited by their ability to pay (i.e., their income and wealth). Thus the views of the rich are given greater weight in the analysis. While the professional literature contains some proposals to rectify this problem, none of them are really satisfactory. The problem of economic inequality may not be quite so significant in all the applications of cost-benefit analysis, for example, in areas like water resources or transportation planning. It is, however, a decisive objection (given prevailing moral sentiments) when life-saving decisions are at issue.

Nor is the Task Force convinced that the fundamental ethical premise of cost-benefit analysis is the appropriate one for its work.

We do not believe the only objective in allocating resources should be the satisfaction of current individual tastes and preferences. Instead, we are persuaded that most citizens want to serve a variety of objectives, including fairness and freedom. We believe more is at stake in transplant policy than giving people what they are willing to pay for. All of us have complicated ideas about right and wrong, and about what we want to do together as a community and a society. In formulating transplant policy, we need to consider such value concerns in a way that a strict cost-benefit approach would make impossible.

The second major approach to quantitative policy analysis is noticeably less ambitious. Called cost-effectiveness analysis, it simply urges us to compare the costs of alternative ways of achieving our objectives. Unlike cost-benefit analysis, which presumes to tell us what ends to seek, this approach merely helps us minimize the costs of achieving whatever ends we select. It is essentially a consistency condition, a way of cross-checking various policy options against each other. We find this approach helpful, and in subsequent sections attempt to compare the costs of organ transplantation with the costs of other life-saving procedures supported by the health care delivery system.

We emphasize, however, that such an analysis is not, in itself, sufficient for making a public policy decision. Society could quite conceivably choose to be inefficient or inconsistent in some specific case (e.g., out of a concern for fairness). Furthermore, the definition of our objectives is not a scientific, but an ethical or political act. No one can tell us from a technical perspective

whether we ought to compare cost-per-life saved or cost-per-year-of-life saved. And a policy that looks good on one basis might not look good on another. Still, we believe there is a general social value in minimizing the costs of doing good things (so that as a society we can do still more good things). Also, there is a value in being direct and explicit about one's presumptions; both empirical and philosophical. We should understand the cost implications of ethical commitments we accept.

A final note on methodology. We have chosen not to consider what is perhaps the most widely used method for the economic valuing of lives, the so-called "human capital" approach. In this method lives are valued on the basis of the sum total of the current expected value of a citizen's future lifetime earnings. We believe society should view its citizens as having an intrinsic value apart from their expected contribution to the economy.

II. The Problems of Estimating the Costs of Transplantation

Comparing the costs of organ transplantation with the costs of other kinds of life-saving medical care is easier said than done. Practically, the requisite data are typically not generated by hospital accounting records, and so are not widely available, either for organ transplants or their alternatives. More fundamentally, there are deep conceptual problems concerning what costs we count and how we count them.

We would like to know what additional real resources the health care system would utilize if we were to follow one or another policy on organ transplantation. We might also like to know who would pay for those added resources, both initially and ultimately. But it is important to stress that the long run cost to the society (that is, the real resource costs) and its distribution might be quite different than the short run fiscal burden. We must worry about inadvertently setting in motion a chain of events that has acceptable results for the next few years, but creates serious difficulties a few years down the road.

The most important conclusion of the analysis which follows is that the net costs of doing transplants, from a system-wide perspective, are not fixed and given. Instead, those costs will vary substantially, depending on how various public and private policy decisions are made. Consider, for example, two scenarios. First, suppose transplants were done by existing institutions that "made room" for the activity by utilizing existing capacity more

efficiently. Alternatively, suppose one or more institutions were to use transplant activity as the reason for a major expansion of plant and equipment. The real resource costs would be much higher in the second situation than in the first.

Even where no new capacity is built, system costs will be influenced by policy choices. For example, how will hospitals be paid for transplants? Do we use the occasion of this new activity to tighten the incentives for efficiency offered by the reimbursement system, or do we use it as an excuse for a substantial relaxation of the fiscal constraints on institutions? Such policy variations will affect more than the size of the immediate bills paid by various third party payers. Differences in reimbursement levels are likely to alter the incentives too, and hence the real efficiency of the hospitals doing transplants. And those changes will in turn affect future system costs.

We must also be very careful about how we describe costs. The literature on high cost patients (Zook and Moore, Shostack and Schroeder) makes it clear that many of those who run up the largest bills do so from repeated admission, not from one acute episode. Much the same is true of transplant patients. The costs of doing the transplant operation itself are relatively minor, whether the operation lasts three hours or twenty-three hours. The real costs come from the post-operative hospitalization and the frequent need to rehospitalize transplant patients to treat various complications. These are very common (averaging more than one per case in most reports on the literature). They include rejection episodes,

complications from the operation itself, and infections that develop because such patients take drugs to suppress their immune system to fight organ rejection, making them more vulnerable to other infections. There are also significant costs in preoperative workups, routine post-operative hospitalization, organ procurement, etc.

The relationship of actual incremental costs to the kind of accounting costs normally available from hospital records will depend on what is happening to the health care system as a whole. If the system is short of beds and hence is expanding, adding transplants is likely to require even more new productive capacity. That additional capacity is quite likely to be more expensive than the average of existing capacity. In such a case, long run incremental costs are likely to be above average costs. On the other hand, when a system is contracting, adding a new activity might only lead the system to contract more slowly than it otherwise would have. In that case average costs are likely to overstate incremental costs.

Deciding what will happen to the system if transplants are not performed is complicated by the fact that the care provided to any population depends on other things beside just the diseases found in that population. The stock of facilities, the number of practitioners available, and idiosyncratic variations in patterns of practice among physicians all play a role in determining utilization. Doctors simply are often not sure exactly what services or procedures to perform on a given patient. Does this ulcer call for surgery or not? Should that recovering heart attack victim spend another day in intensive care? How likely is it that a given set of laboratory tests will tell

anything useful? No one can say for certain. As a result, judgment, intuition and experience all play a major role in treatment decisions.

Because of the informal nature of such clinical decision making, the availability of practitioners and facilities can easily play both a conscious and an unconscious role in influencing how patients are cared for. Areas where there are more surgeons tend to have more surgery than epidemiologically comparable areas with fewer surgeons. Areas with more hospital beds per thousand residents tend to have more bed days per resident per year. Practice responds to capacity as much as the other way around.

Hence we cannot assume when we add or subtract a new service that use in the rest of the system will not change. Perhaps if we eliminate some service, practitioners and institutions will find something of lesser, even dubious value to put in its place. In that case eliminating the activity would save less than we anticipated. Alternatively, just because we add an activity doesn't mean system costs will rise by the full amount of the direct costs of the new services: other uses might be compensatorily diminished, especially if the system's capacity to expand is constrained.

This last point underlines the need, if possible, to trace out the cost effects of transplants beyond the boundaries of the institutions directly involved. Hospital A may say it will perform less of certain kinds of other surgery if allowed to do transplants. But some or all of the procedures it doesn't do may simply be performed elsewhere. The total system impact of such "spillover" costs could be very significant.

Total costs will be a function not only of the unit costs but also of volume; and availability of facilities and financing will impact on volume. This certainly seems to have been the case with the End Stage Renal Disease (ESRD) Program which since 1972 has, under Medicare, paid for most of the costs of both kidney dialysis and kidney transplantation. As a result, the number of facilities that offer such services has increased greatly, as has the patient volume. In the process, the clinical criteria by which patients were judged appropriate candidates for one or the other treatment (e.g. age, the presence of other diseases, etc.) have expanded.

Nor will we necessarily be able to avoid dealing with the link between capacity and use by relying on the supply of organs to be the limiting factor on heart and liver transplantation. The existing large volume of kidney transplants with cadaver organs points to the existence of a substantial pool of potential hearts and livers once the necessary arrangements for procuring them are established. Instead, financing and facility availability, given their effect on implicit and explicit judgments and criteria for patient selection, could be the major determinent of volume, and hence of total costs.

The volume of services provided, and its distribution among institutions, will also affect cost-per-case. For example, if specialized laboratory equipment is utilized full time, costs per case will be lower than if a number of providers all acquire and maintain separate, and under-utilized facilities. Similarly, if multiple institutions pay the costs of having extra staff on call, average costs will be higher than if only one institution does so (or if a

joint team is maintained). Again, this tells us that "the costs" of transplantation may be quite sensitive as to how this activity is carried out.

The costs of a transplant program are not simply the costs incurred by those operated on. Typically pre-operative screening costs are incurred for many more individuals and are part of the costs "per case treated." And if we want to take account of the costs on a "per life saved" basis, we have to take account of the costs incurred by unsuccessful recipients. Only very few estimates in the literature appear to take these points seriously, however.

On the other side, would-be transplant recipients without transplants are likely to die in the short run, incurring some costs in the process. So gross cost is not net cost from a system perspective. Yet, not all of the costs of caring for patients who otherwise would die are saved when they are transplanted. Some of their "dying" costs are incurred anyway in the pre-transplant period. It also will depend upon how the system responds to the fact that they are no longer there to be cared for. Are expenses really decreased because of their decreased demand, or are other patients hospitalized longer to take their place? We cannot assume that the bills paid by non-transplanted patients represent easily realizable cost savings if only they had been transplanted instead.

III. The Costs of Organ Transplantation

There are at least four different ways the "costs" of organ transplantation have been defined.

- bills-taken directly from hospital financial records;
- fully allocated average costs-usually based on reimbursement cost reports;
- direct costs-derived from studies of actual resource use; and
- incremental costs-which have been estimated by asking which costs would be incurred only if transplantation were performed.

The published medical literature is often too elliptical to be much help for sophisticated analysis. Instead, various work done in Massachusetts is often the best available. We begin with livers and then proceed to hearts.

For liver transplants the only cost numbers available in the published literature come from the Pittsburgh group that has done by far the most procedures nationally. In one publication (Starzl 1982) they report, "The approximate average cost...has been $55,000 (range $23,000 to $150,000, p. 633)." In another paper from the same group, the same year (Van Thiel, 1982), we are told, "The average hospital bill for patients was $30,636...physician charges...averaged $98,000,." While the reports are so brief as to make their interpretation difficult, it appears that they are based on bills not costs. They also exclude initial workup costs, readmissions for complications, the costs of organ procurement and the costs of cyclosporin A. Given all these limitations, they tell us very little about the the incremental cost implications of various alternative possible state transplant policy decisions in Massachusetts.

Of substantially more interest is the work of the prior Task Force on Liver Transplantation in Massachusetts. That group developed an estimate of $238,800 per transplant patient alive one year after transplantation. This was based on a cost-per-case treated of about $170,000 and a 70% one year survival rate.

From our discussions with those who worked on the estimates, it seems that they are meant to reflect fully allocated average costs, rather than direct or incremental costs. Of the $167,200 per case treated, only $9,000 is for the surgery itself. More than one quarter of the cost ($43,200) is attributed to readmission due to complications. Nearly half the total (almost $80,000) is attributed to ancillaries (lab, blood, IV, radiology, social work, physical therapy, etc). Only $11,000 is allocated to physician fees, and apparently this does not include payment for the surgeon. While the cost per readmission is expected to be $96,000, it is assumed that only 45% of all patients would be readmitted, making the average readmission cost $43,200.

A second reasonably detailed cost estimate has been prepared by Massachusetts Blue Cross-Blue Shield as part of an effort to determine premium rates for their transplant insurance policy. Their average estimates assume slightly longer post-operative hospitalization (61 vs. 54 days), higher physician fees ($18,500 vs. $11,000) and approximately twice the extent of post-discharge rehospitalization for complications. (They estimate the rate of rehospitalization is .5, and the average L.O.S. for those rehospitalized is 180 days. The prior Task Force assumed rehospitalization L.O.S. at 90 days.) Thus

the Blue Cross-Blue Shield one year cost estimate is close to $270,000. This is also a fully allocated average cost figure.

Liver transplant cost estimates can also be found in the various applications that have been filed by hospitals in the Commonwealth proposing to perform such services. In particular, there are such estimates both in the original Massachusetts General Hospital (MGH) application and in the amended application filed last October by the consortium called "The Boston Center for Liver Transplantation." The original MGH application came to a cost of about $38,000 per transplant with a volume of 10 per year. The consortium arrived at $60,000 per adult case (with no specified volume).

The reasons these estimates are so much lower than those of Blue Cross and previous Task Force are not difficult to discover. Most importantly, the hospital estimates are for direct costs only, not fully allocated average costs. Hence, they contain no allowance for any capital costs (either for plant or equipment) nor any allowance for central administrative and overhead expenses. There are also many differences of detail. For example, the original MGH proposal estimates 81 days per case, 46 of these ICU days. The consortium allows 65 days, only 12 of which are in a prior ICU. The Task Force's guess was 61 days, 16 of these ICU, plus a 45% chance of a 30 day ICU readmission, for an average total of 74 inpatient days per recipient. The consortium estimates only $20,000 in ancillary costs prior to rehospitalization (but again these are only for labor and supplies, no overhead) vs. the about $50,000 for the Task Force. The original MGH number is quite a bit smaller still. The consortium estimate includes

no physician compensation at all, and the MGH total includes only the cost of an anesthesiologist. This can be compared to the $11,000 and $28,000 respectively in the prior Task Force's report and the Blue Cross study.

The heart transplant literature is more extensive than that on liver transplants because more groups have experience with the former procedure. The most detailed cost reports are from the Stanford group (Oyer et. al,, 1980; and Pennock et. al., 1982). The first paper provides data on 27 patients treated between May of 1978 and April of 1979. The latter paper reports on 97 patients treated between October 1973 and April 1979 (including the 27 covered in the first report) and 13 patients treated between May 1980 and December 1980. The latter reflect costs after cost reduction efforts instituted on May of 1980. The first paper implied first year costs of $140,000 plus surgeon's fees, the latter $130,000; but the follow up data is only based on experience with patients treated in 1979 or before. The lower cost in the larger sample suggests that the 27 patients reported in the first paper did somewhat worse than the longer run average. The cost-reducing efforts after May 1980 appear to have lowered initial hospitalization costs about 15%, primarily by reducing ancillary costs (which were half the total) by about 30%. There is not enough evidence yet to see whether the $18,000 annual costs of inpatient and outpatient follow-up, characteristic of the late 1970s, will persist. These are not trivial costs, however, and they bring the five year cost per case to about $200,000.

A less detailed report, on a series of 32 patients treated at the University of Arizona (Copeland et. al., 1984) over a period of four years, reports a cost of $58,000 as "the total cost...until discharge." The Arizona analysis apparently excludes the outpatient follow-up and readmission costs which for the first year generated nearly $30,000 for each patient in the Stanford study. In addition, daily costs of Arizona were apparently $761 vs. $1966 at Stanford, and initial stays 10 days shorter. The first factor would account for about $45,000, the latter $15,000 of the differences in costs between the two studies. Again "costs" here apparently means "bills."

There are also cost reports in the literature by Dr. Richard R. Lower's group that operates at both the Medical College of Virginia in Richmond and the McGuire V.A. Medical Center in the same town (Thomas and Lower, 1978, Szentpetery, et. al., 1984). The latter paper estimates the cost of transplantation at "$23,275 more than the cost of performing uncomplicated cardiac surgery at the Center" a figure which apparently includes primarily the costs of organ procurement and special medication. It appears to make no allowance for direct and indirect inpatient costs, and includes no allowance for rehospitalization, etc. The earlier paper apparently estimates the total costs of each transplant patient as being "in the range of $20,000 for the transplant year and $2,000 year thereafter." These numbers are so much lower than the other more detailed estimates available in the literature, and sufficiently inconsistent with the group's own later numbers, that it seems likely they were not based on an in-depth analysis.

When we get to the various unpublished (i.e. hospital and Blue Cross) studies of heart transplantation done in-state we find some significant disagreements. Apparently since the introduction of Cyclosporin A, the Stanford group has managed to substantially reduce the risks of both rejection and secondary infection. Indeed, they report (personal communication with Dr. Phillip Oyer) that their length of stay for the last 100 transplant patients, since using this drug, has been 38 days (versus 66 as recently as 1980). And in the most recent experience (the 12 cases done in 1983) post-operative L.O.S. appears to have fallen to 30 days. In their estimates of the costs of heart transplantation, Blue Cross used this latter L.O.S. estimate. In addition, Blue Cross used the reduced ancillary-to-room-charge ratio experienced in Stanford since the 1980 cost reduction efforts. On this basis, Blue Cross estimated the one year cost of a heart transplant at $124,000, assuming that follow-up hospitalizations and readmissions the first year averaged 12 inpatient days as opposed to the pre-April 1979 Stanford experience of 22 days.

The Brigham and Women's July 1983 proposal to Blue Shield yields an even smaller number, $30,000 in variable cost and $60,000 in fixed cost per case. This is based on a total initial hospitalization of only 28 days (including two days pre-operative) and with only an average of 5 days of rehospitalization assumed for the first year. Forecast ratios of ancillary costs are also very low. Stanford's latest numbers suggest ancillary to room cost rates of just over 1:1; Brigham and Women's used 3:4. Thus, in a whole series of respects, the Brigham and Women's estimate seems very optimistic from a total cost perspective.

The most recent hospital cost estimates are supplied by the Boston Center for Heart Transplantation. Their new D.O.N. application estimates an increased cost per transplant of $53,105. Since no backup figures are provided, it is impossible to know exactly how this number was derived or what assumptions it reflects. It does appear to be some sort of direct cost number, however. It is worth noting that all three hospitals (regardless of their significant differences in pay labels, cost positions and projected volumes) all estimated exactly the same per case cost in each year from 1985 through 1987. This raises questions about the extent to which this number reflects a serious "best-guess estimate" of what will actually take place in each of the various institutions, or is merely a compromise figure put forth for negotiating purposes.

What does all this tell us about the behavior of short and long run incremental costs, the numbers of primary interest to this state's policy makers? How much will total health care delivery system costs in the Commonwealth rise as a result of various levels of transplant activity?

There is still a substantial amount of uncertainty as to what transplantation will involve on the medical side, never mind on the financial side. Are the very good recent Stanford results (and the Pittsburgh results for livers) going to hold up over time and can they be duplicated elsewhere? For example, does the 1983 30 day L.O.S. for heart transplants represent the result of a "lucky streak", in which case using it as a long run estimate is too optimistic. Similarly, it may be that because of its reputation Stanford gets the best cases,

and so gets better results than can be expected elsewhere, in terms of both survival and L.O.S. It also may be that Stanford (and Pittsburgh in the case of livers) has developed skills and techniques that are not readily transferable. As recently as 1982 Dr. Richard Lower of Virginia was expressing puzzlement in print that his 1 year survival rate was 40% vs. the more than 60% rate at Stanford.

Uncertainty of medical results implies uncertainty about costs since the forecast costs of transplant procedures depends critically on what one assumes about post-operative hospitalization and rehospitalization. The Blue Cross study, for example, forecasts 12 days of rehospitalization, on average, for heart transplant recipients, and 90 days average for liver transplant recipients. These numbers are likely to be significantly influenced by the skill of the care team, and the case mix accepted into the program.

Several other difficulties stand out with all of the available estimates. First, they take no account of the screening costs associated with the patients who are never accepted into the program. These costs could be very substantial. At least one study (Reiss et al) estimates these costs at Stanford as running at $20,000 per case in the late 1970's; $10,000 of which was incurred before the patient was referred. Since Stanford only accepted one patient in ten in 1977 (the only year for which these data are available) the cost of screening alone could be nearly equal to the costs of the entire rest of the program, doubling the estimates reviewed thus far! Even at a 1 in 4 acceptance rate and $10,000 net cost per patient screened, this source of costs is quite significant on a per-case-treated basis. For

livers, (although we have even less information) the costs are likely to be higher since more of those patients must be hospitalized during evaluation.

On the other side of the ledger, none of the estimates include the cost of savings from not caring for the terminal illness of those who are transplanted. For hearts this cost is likely to be modest (personal communication with Dr. Ward Cassells) since perhaps half of those with cardiomyopathy who are well enough to be transplant candidates would die without hospitalization. Making plausible assumptions for the rest, Dr. Cassells gets numbers from $10,000 to $15,000 per case of fully allocated average costs, for death without transplant. These are noticably less than the costs omitted in the estimates we have reviewed from the failure to count the screening costs of those screened out. Death costs for liver patients will be higher, perhaps two to four times as high; but screening costs could outweigh these new costs as well.

Since hospitalization costs dominate the overall case costs of transplantation, the costs per case (as the Arizona-Stanford contrast shows) will depend on the daily costs in the hospital in which patients are cared for. Unfortunately, Boston is a relatively expensive part of the country from a hospital cost point of view. The hospitals concerned have new plants, must pay costs associated with teaching related activities, pay relatively high wage rates, etc. But apart from which hospital does the work, the actual resources used in transplantation will be greatly affected by how the transplant hospital conducts its activities. Stanford's report of a 30% decline

in ancillary costs after instituting cost control efforts reinforces this point. Will Boston hospitals be like Stanford before or after it instituted efforts to curtail the ancillary use associated with transplants? The answer will surely depend in part on whether or not institutions undertaking to do transplants do so in the context of incentives to control costs.

As to what incremental costs the state can expect, the literature makes it clear, as noted previously, that these will depend on how the system responds, and is allowed to respond. If transplantation becomes such a high volume activity that it leads to an expansion in the state's health care system, the cost of a liver transplant per case is likely to be more than the $160,000-240,000 range allocated average cost for the first year per patient treated, the range suggested by the prior Task Force and Blue Cross. Likewise the $120,000-140,000 range suggested by the published Stanford studies and Blue Cross could prove to be an underestimate for heart transplant costs. The estimates in those studies are based on existing averages. These are likely to be well below the long run incremental costs of adding new plant and equipment at today's all-time high, and rapidly escalating construction, equipment and financing costs. They also contain the partially off-setting screening costs incurred and death costs avoided.

On this same basis, <u>if we have 70% survival for one year, we get costs of $230,000-340,000 per liver transplant patient alive at the end of one year and $170,000-200,000 per one year survival for heart transplants</u>. If we assume a 5 year average life expectancy and from

$10 to $20 thousand in annual costs after the first year, we get numbers anywhere from $35,000 to $60,000 per year of life saved by either kind of transplant program.

At the opposite end of the spectrum, the system's incremental costs could even be below the $60,000 estimated by the Liver Consortium, or the $30,000 for hearts estimated by Brigham and Women's. To do this, both individual institutions and the system as a whole would have to give up providing other services in order to make room for organ transplants. This is so even though the Brigham's total costs are almost certainly quite optimistic, since some of the costs they cite as incremental (e.g. nursing) are not incremental in the postulated circumstances.

The challenge to state health policy makers and regulators with regard to organ transplantation is thus two-fold:

- First, to make sure that transplantation is, to the largest extent possible, undertaken within the limits set of existing resources, so that adding this service does not lead to an expansion of the total delivery system.
- Second, to insure that whatever care is given up in the process is of doubtful value, that is "gold plated" or unnecessary care, with little or no positive payoff for the patient. In that case the decision to do something else with the resources that previously produced such care (whether we use it for transplants or something else) will be much less difficult to make.

This leads to an ironic realization. Either one has to believe that there is non-trivial inefficiency in the current system, or one

has to believe organ transplantation will be very costly in social and economic terms. If there is no waste today, and we add transplantation, we will either have to expand the delivery system or give up valuable services. On the other hand, there is reason to believe that the state is overbedded, particularly in Boston, that lengths of stay are too long, and that too much cost-ineffective use is currently made of intensive care and sophisticated ancillary services. The high concentration of teaching hospitals in Boston appears in part responsible for these conditions. The bright side is that current inefficiency makes possible the careful accommodation of a modest volume of transplant activity at reasonable cost, provided its introduction is carefully controlled.

From that point of view, the existence of the total revenue limits under Chapter 372 have the effect of making transplantation a much less risky step, from a system cost standpoint, than it otherwise might be. The very existence of "MAC" limits make it possible to pressure providers to substitute transplantation for other activites rather than simply adding it on to existing functions. However, the Chapter 372 exemption system could also be used to grant major increases to transplanting hospitals. If that were to happen, substantial increases in real costs would most assuredly follow. Thus the ultimate incremental costs to the state from transplantation will depend critically on how the regulatory process controlling hospital expenses is handled.

In the narrowest sense, one could argue that only the costs of special medication and the organ itself (perhaps $20,000 per case)

will be truly incremental costs to the system. Hence one might claim that only the $20,000 should be recognized as an exception (i.e. an addition to the MAC) for each transplant. Indeed, in principal, one could go even further and allow no increase; insisting instead on compensatory reductions for these costs as well. Just how "tight" to be on the reimbursement side however requires a judgment call on just how much "slack" there is in the system and whether we should try to use the occasion of transplantation to squeeze that slack out of the provider institutions. The Task Force has not had the resources to perform the comprehensive review of various hospital's services and finances that required to make such a decision.

The capacity that will be foreclosed from other uses in a hospital with even a small transplant program is significant. At 45 ICU days/case/year, 12-14 procedures a year would mean an average of two full ICU beds. Given this, there is a risk that transplantation could cause "spill over" effects which will show up at other institutions. The Chapter 372 mechanisms will have to be employed vigorously to insure that any such effects do not become the basis for successful exception requests. Otherwise institutions that are not themselves performing transplants will have every incentive to encourage volume increases and try to use "transplantation spillover" as an excuse for increasing their own revenue flows.

IV. The Costs of Other High Cost Medical Procedures

How do transplant costs compare with those of other so-called "high cost" medical procedures? In Table I we present a summary of the results from a literature review on the costs of a variety of conditions and procedures. We present these comparisons in two ways: cost-per-case, and cost-per-year-of-life saved. In our view the two measures are differentially relevant, depending upon the grounds on which a resource allocation decision is made. Cost-per-year-of-life seems most applicable in an efficiency-oriented, cost-effectiveness, context. It tells us what we get for what we spend. Cost-per-case seems more relevant when we want to judge claims based on rights or justice; claims that we should use certain resources regardless of consequences. Rather than take sides, we present both.

Neo-natal intensive care is one area that has come in for a great deal of attention in recent years with regard to its cost effectiveness. Especially controversial has been the care of very low birth weight infants, below 1000 grams. There are no less than six studies in the literature of such services. Five of these (except Kaufman and Shepard) are based on bills, not on actual cost analysis. The oldest paper, Pomerance et. al., reports on a study of 75 infants at Cedars-Sinai Medical Center in Los Angeles between 1973 and 1975. McCarthy looked at 174 cases at Childrens Hospital in Denver in 1976. Shannon studies 53 infants, all in respiratory distress, at Massachusetts General Hospital in Boston during 1974. Phipps considered 1185 admissions to University of California,

San Francisco from 1976 to 1978. Kaufman and Shepard did an in depth cost analysis of 10 infants at Boston Hospital for Women in 1977 and Boyle et. al. studies 259 infants both between 1973 and 1977 in Hamilton County, Ontario, 70% of whom were treated at a regional center and the other 30% were seen in two affiliated hospitals.

The studies show an average cost-per-case of between $8,000 and $11,000 for broad samples of newborns in intensive care, and $16,000 to $25,000 cost per case for infants weighing below 1000 grams. The once exception is Boyle's study, whose very low average cost-per-case reflects a large early mortality rate, and hence low average costs, for the low weight group. If we assume survivors have life expectancies of from 50 to 65 years, all studies imply less than $1200 or less (usually much less) per year of life saved. These numbers are, depending on which basis of comparison we choose, an order of magnitude (and in some cases two orders of magnitude) below the comparable figures for heart and liver transplants.

When we shift our attention to intensive care for adults, we find four relevant studies. Three of the four (Cullen et. al., Thibault et. al., and Detsky et. al.) were done at the Massachusetts General Hospital. The sample for the first study (Cullen) was taken in 1972, and comprised 226 patients in the most acute of four diagnositic categories. The samples for the last two studies were taken in 1977 to 1979 and include all admission to certain services. Although we are not told explicitly, it appears there is some overlap in the 2693 patients studies by Thibault et. al. and the 1831 examined by Detsky et. al. Chasson in contrast examined 489 surgical intensive

care patients from a teaching hospital in Los Angeles in 1977. For several of the studies we have extracted cost numbers for various sub-groups as well.

With one exception, none of the groups analyzed in Table I had costs-per-case over $25,000, again more-or-less an order of magnitude below heart and liver transplant costs. But given that one year mortality rates in some cases were well above 50% for some sub-segments, we do find estimated costs per survivor in the neighborhood of $50,000. However, these are still well below the costs associated with transplants, and well above those found in most neonatal intensive care studies. Finally, depending on what one assumes about life expectancy of survivors of such ICU care (5 years seems a not unreasonable lower bound), one can get numbers as high as $10,000 per year of life saved. These are well below the $30,000-60,000 for heart and liver transplant recipients. Longer life expectancies would, of course, imply lower per year costs.

The two studies of the third condition in Table I, end stage renal disease, are not themselves actual studies of particular patients. Instead both of them rely on government data (bills paid under the ESRD program). In both cases, the primary concern of the studies was to determine the impact on nationwide total costs of changes in treatment patterns. The costs of each treatment modality were estimated with that goal in mind.

As is clear from the Table, center dialysis does have costs, or at least bills, that are noticeably higher than those of any other procedures reported therein. The costs per year of life saved, however, are still well below those of transplantation. This is

because dialysis patients have over 8 years of life expectancy on average while relatively few transplant patients survive that long. Furthermore, the annual costs of home dialysis are actually below the higher estimates of the annual costs of post-heart-or-liver-transplant care, completely apart from the $120,000 to $240,000 first year costs of the transplant itself. Note also that Roberts et. al.'s relatively high numbers for renal transplant costs include the costs of patient maintenance on dialysis while waiting for transplantation, as well as a prorated share of the costs of retransplantation for those whose first graft does not succeed.

Finally, there are three studies which are the only ones of their respective conditions. O'Donnell et. al. examined 32 patients admitted for acute variceal bleeding at New England Medical Center in 1977-79. Smith et. al. studied 42 patients in a Rhode Island state-wide program to care for hemophilia in 1979-80. And Gale et. al. studied two hundred and six bone marrow transplant patients treated for leukemia at UCLA Medical Center in the years before 1979.

These three investigations reveal just how important it is to compare costs in various ways, given the different cost and benefit structures of different treatments for different diseases. As reported by Smith, treatment for hemophilia costs about $10,000 per year, comparable to the costs Gale found for marrow transplantation. Unforunately Smith's study does not report life expectancies, so it is not possible to compute lifetime costs per case for this treatment. But this number could be substantially more than the $60,000 lifetime costs Gale found in marrow transplants if the hemopheliacs' lifetime

expectancies were 8-12 years or more. This comparison shows again how total costs of caring for chronic conditions can be greater than those of dealing with acute conditions, especially when such treatment modes are successful, and the patients survive long enough to receive significant amounts of treatment.

Finally, O'Donnell's study of variceal bleeding reveals a particular aspect of cost calculations when mortality rates are very high. The 10 patients treated in his sample on an emergency basis all died. This makes the cost per year of life in this class literally infinite! This suggests that such expenditures have to be justified on some notion of justice or fairness, not cost-effectiveness. Perhaps we do them on the basis of what care consitutes the "decent minimum" to which citizens are entitled (as discussed by the President's Commission).

In summary, on both a cost-effectiveness basis (cost-per-year-of-life) and a cost-per-case basis, heart and liver transplantation is likely to be, in almost all cases, substantially more expensive than almost everything we currently do in the medical care system. There are only two exceptions to this generalization. First, if one makes optimistic assumptions, the five year cost per case of heart transplants might be low enough to be comparable to the five year costs of center hemodialysis. But the cost-per-year-of-life saved is still noticeably higher for transplantation. Also, it is perfectly reasonable to argue that center dialysis is so much less cost-effective than the alternative treatments for ESRD that it should not generally be pursued in any event. To put it crudely, the fact that we as a society make one mistake in medical care resource

allocation does not justify making another, especially one even more costly from a cost-effectiveness viewpoint.

The other exception to the rule "transplants cost more" is the treatment of certain sub-classes of very acutely ill individuals in intensive care. Their costs-per-case, however, are well below transplantation even if their costs-per-year are equal or above, especially if we can identify subsamples for which the mortality rates are high enough. Yet if the care of such individuals is justified on the basis of fairness, not effectiveness (as presumably it must be since it is so cost-ineffective), then total cost is the relevant measure for comparative purposes. On that basis, transplants will cost two to four times as much per case as the costs of even the sickest patients in intensive care, with liver transplants looking particularly expensive.

The entire preceding discussion has focused on fully-allocated-average-costs, often as imperfectly measured by hospital bills. The incremental costs of transplants, like those for any of these other procedures, could be noticeably less if the added volume is accommodated within existing capacity. In that case, as we have stressed repeatedly, marginal or incremental costs could be much lower than average costs. But those costs, for any procedure, will depend on how the health care system in a given area responds to the increased demand. Consequently, it seems most appropriate to compare procedures on a fully-allocated-average-cost basis that provides an insight into the relative system burden imposed (or problem posed) by the options in question. From that perspective, heart and liver transplants are exceptionally, and uniquely, expensive.

TABLE I

Costs of Various Treatments

	Per Case Treated ($ in thousands)	Per Life Saved ($ in thousands)	Per Year of Life ($ in thousands)	Comments
Neo-natal Intensive Care				
Pomerance *	25	62		<1000 gm birthweight
McCarthy *	11	13		all admissions
	16	26		<1000 gm birthweight
Shannon *	10	14		respiratory distress babies
			$.13 to $1.2	
Phibbs *	8	9		all admissions
	19	32		<1000 gm birthweight
Kaufman*	10	26		<1000 gm birthweight
Boyle *	3	14		<1000 gm birthweight
	11	14		>1000 gm birthweight
Adult Intensive Care				
Cullen *	14	52		•sickest 10% of ICU admissions
Thibault*	5	7		•2700 patients
	17	47		•respiratory failure
	11	20		•renal failure
	9	47		•hepatic failure
			$.6 to $10	
Detsky*	5	6		•full sample
	7	28		•worst class
	15	24		•second worst class
Chassin*	15	20		•total sample
	32	51		•renal failure

* main author, see references for full citation

Table I (cont.)	Per Case Treated ($ in thousands)	Per Case Saved ($ in thousands)	Per Year of Life ($ in thousands)	Comments
E.S.R.D.				
Strange*	202		26.7	• center dialysis
	83		17	• home dialysis
	50-68		13-16	• cadaver transplant
Roberts*	209		24	• center dialysis
	130		13	• home dialysis
	123		15	• cadaver transplant
	108		7	• living related transplant
Hemophelia				
Smith*			10	
Variceal Bleeding				
O'Donnell*	35	54	18.4	average survival 36 months
	40	infinity		
Bone Marrow Transplants				
Gale*			12	

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IV. PATIENT SELECTION AND RATIONING SCHEMES

In an era of scarce resources, decisions concerning which patients will receive the resources must be made.[1] Unless we decide to make heart and liver transplantation available to no one, or available to everyone, some rationing scheme must be used to choose among potential transplant candidates. The debate has existed throughout the history of medical ethics. Traditionally it has been usually stated as a choice between saving one of two patients, both of whom require the immediate assistance of the only available physician to survive. More recently national attention was focused on decisions regarding the rationing of kidney dialysis machines when they were first used on a limited basis in the late 1960's. As one commentator described the debate within the medical profession:

> Shall machines or organs go to the sickest, or to the ones with most promise of recovery; on a first-come, first-served basis; to the most `valuable' patient (based on wealth, education, position, what?); to the one with the most dependents; to women and children first; to those who can pay; to whom? Or should lots be cast, impersonally and uncritically?...[2]

In Seattle, Washington an anonymous screening committee was set up to pick whom among competing candidates would recieve kidney dialysis. One lay member of the screening committee is quoted as saying:

> The choices were hard...I remember voting against a young woman who was a known prostitute. I found I couldn't vote for her, rather than another

> candidate, a young wife and mother. I also voted against a young man who, until he learned he had renal failure, had been a ne'er do-well, a real playboy. He promised he would reform his character, go back to school, and so on, if only he were selected for treatment. But I felt I'd lived long enough to know that a person like that won't really do what he was promising at the time.[3]

When the biases and "selection criteria" of the committee were made public, there was a general negative reaction against this type of arbitrary device. Two experts reacted to the "numbing accounts of how close to the surface lie the prejudices and mindless cliches that pollute the committee's deliberations," by concluding that the committee was "measuring persons in accordance with its own middle-class values." The committee process, they noted, ruled out "creative nonconformists" and made the Pacific Northwest "no place for a Henry David Thoreau with bad kidneys."[4]

To avoid having to make such explicit, arbitrary, "social worth" determinations, the Congress in 1972 enacted legislation that provided federal funds to cover virtually all kidney dialysis and kidney transplantation procedures in the United States.[5] This decision, however, simply served to postpone the time, which is fast arriving, when identical decisions will have to be made about candidates for heart and liver transplantation in a society that does not provide sufficient financial and medical resources to provide all "suitable" candidates with the operation.

There are four major approaches to rationing scarce medical resources: (1) the market approach; (2) the selection

committee approach; (3) the lottery approach; and (4) the "customary" approach.[6]

The Market Approach

The market approach would provide an organ to everyone who could pay for it out of their own funds or through private insurance. It puts a very high value on individual rights, and a very low value on equality and fairness. It has properly been criticized on a number of bases, including that the transplant technologies have been developed and are supported with public funds, that medical resources used for transplantation will not be available for other, perhaps higher priority, care, and that financial success alone is an insufficient justification for demanding a medical procedure. Most telling, however, is its complete lack of concern for fairness and equity. In the words of the President's Commission for the Study of Ethical Problems in Medicine:

> In light of the special importance of health care, the largely underserved character of differences in health status, and the uneven distribution and unpredictability of health care needs, society has a moral obligation to ensure adequate care for all.[7]

A "bake sale" or charity approach that requires the less financially fortunate to make public appeals for funding is demeaning to the individuals involved, and to our society as a whole. Rationing by financial ability says we do not believe in equality and that we do

believe that a price can and should be placed on human life and that it should be paid by the individual whose life is at stake. Neither belief is tolerable in a society in which income is inequitably distributed.

The Committee Selection Process

The Seattle Selection Committee represents a model of the committee process. "Ethics Committees" set up in some hospitals to decide whether or not certain handicapped newborn infants should be given medical care may represent another. These committees have developed because it was seen as unworkable or unwise to explictly set forth the criteria on which selection decisions would be made. But only two results are possible, as Professor Guido Calabrezi has pointed out: either a pattern of decision-making will develop or it will not. If a pattern does develop (e.g. in Seattle, the imposition of middle-class values), then it can be articulated and those decision "rules" codified and used directly, without resort to the committee; if, on the other hand, a pattern does not develop, the committee is vulnerable to the charge that it is acting arbitrarily, or dishonestly, and therefore cannot be permitted to continue to make such important decisions.[8]

In the end, public designation of a committee to make selection decisions on vague or non-specific criteria will fail because it too closely involves the state and all members of society in explicitly preferring specific individuals over others, and in disregarding the

interests those others have in living. It thus directly undermines, as surely as the market system does, society's view of equality and the value of human life.

The Lottery Approach

The lottery approach is the ultimate equalizer which puts equality ahead of every other value. This makes it extremely attractive, since all comers have an equal chance at selection regardless of race, color, creed, financial status, etc. On the other hand, it offends our notions of efficiency and fairness since it makes no distinctions among the strength of the desires of the candidates, their potential survival, their quality of life, etc. In this sense it is a "mindless" method of trying to solve society's dilemma which is caused by its unwillingness or inability to spend enough resources to make a lottery unnecessary. By making this macro spending decision clear to all, it thereby also undermines society's view in the pricelessness of human life. A first-come, first-served system is a type of lottery since referral to a transplant program is generally done randomly in time. Nonetheless, higher income groups may have quicker access to referral networks and thus have an inherent advantage over the poor in a strict first-come, first-served system.[9]

The Customary Approach

Traditionally, society has attempted to avoid explicitly

recognizing that we are making a choice not to save individual lives because it is too expensive to do so. As long as such decisions are not explicitly acknowledged, they can be tolerated by society. For example, until this year there was said to be a general understanding among general practitioners in Britian that individuals over 55 suffering from end-stage kidney disease not be referred for dialysis or transplant. In 1984, however, this unwritten practice has become highly publicized, with figures that show a rate of new cases of end-stage kidney disease treated in Britian at 40 per million (versus the U.S. figure of 80 per million) resulting in 1500-3000 "unnecessary deaths" annually.[10] This has, predictably, led to movements to enlarge the National Health Services budget to expand dialysis services to meet this need, a more socially acceptable solution than permitting the now publicly recognized situation to continue.

In the U.S., the "customary" approach permits individual physicians to select their patients on the basis of "medical criteria" or "clinical suitability" which may, in fact, contain much that we would consider "social worth" criteria if it was explicitly spelled out. For example, one criterion, common in the transplant literature, requires an individual to have sufficient family support for successful aftercare. This discriminates against individuals without families and those who have become alienated from their families.[11] The criterion may be relevant, but it is hardly medical.

Similar observations can be made about "medical" criteria that include I.Q., mental illness, criminal records, employment, indigency, alcoholism, drug addiction, or geographical location. Age is perhaps

more difficult, since it may be at least impressionistically related to outcome. But it is not medically logical to assume that an individual who is 49 years old is necessarily a better medical candidate for a transplant than one who is 50 years old. Unless specific examination of the characteristics of older persons that make them less desirable candidates is undertaken, such a cut off is arbitrary, and thus devalues the lives of older citizens. The same can be said of blanket exclusions of alcoholics and drug addicts.[12]

In short, the customary approach has one great advantage for society and one great disadvantage: it gives us the illusion that we don't have to make choices; but the cost is mass deception, and when this deception is uncovered, we must deal with it either by universal entitlement or by choosing another method of patient selection.

A Combination of Approaches

Any approach selected, to be socially acceptable, must be fair, efficient, and reflective of important social values. The most important values at stake in organ transplantation are fairness itself, equity in the sense of equality, and the value of life. To promote efficiency, it is important that no one receive a transplant unless they are likely to obtain benefit from it in the sense of increased length of life at a reasonable level of functioning.

Accordingly, it is appropriate for there to be an initial screening process that is based exclusively on medical criteria designed to measure the probability of a "successful" transplant, i.e.

one in which the patient survives for a considerable length of time and is rehabilitated. Of course there is room in "medical criteria" for social worth judgments, and there is probably no way to avoid this completely. For example, it has been noted that "in many respects social and medical criteria are inextricably intertwined" and that therefore medical criteria might "exclude the poor and disadvantaged because health and socioeconomic status are highly interdependent."[13] Roger Evans notes an example. In the End Stage Renal Disease Program, "those of lower socioeconomic status are likely to have multiple comorbid health conditions such as diabetes, hepatitis, and hypertension" making them both less desirable candidates and more expensive to treat.[14]

To prevent the gulf between the haves and have nots from widening, we must make every reasonable attempt to develop medical criteria that are objective and independent of social worth categories. One minimal way to approach this is to require that medical screening criteria in the state be uniform and that the criteria adopted be reviewed and approved by an ethics committee with significant public representation, filed with a public agency, and made readily available to the public for comment. In the event that more than one hospital in the state is offering a particular transplant service, it would be most fair and efficient for the individual hospitals to perform the initial medical screening themselves (based on the uniform, objective criteria), but to have all subsequent non-medical selection done by a method approved by a single selection committee composed of representatives of all hospitals engaged in the particular transplant

procedure, as well as members of the Department of Public Health and significant representation of the public at large.

As this implies, after the medical screening is performed, there may be more acceptable candidates in the "pool" than there are organs or surgical teams to go around. If (and only if) this is so, some selection among waiting candidates will have to be made. This situation occurs in kidney transplantation now, but since the organ matching is much more sophisticated than in hearts and livers (permitting much more precise matching of organ and recipient), and since dialysis permits individuals to wait almost indefinitely for an organ without risking death, the situations are not close enough to permit use of the same selection criteria for hearts and livers.[15] On the other hand, to the extent that organs are specifically tissue and size-matched and fairly distributed to the "best matched" candidate, the organ distribution system itself will be a natural random allocation system.

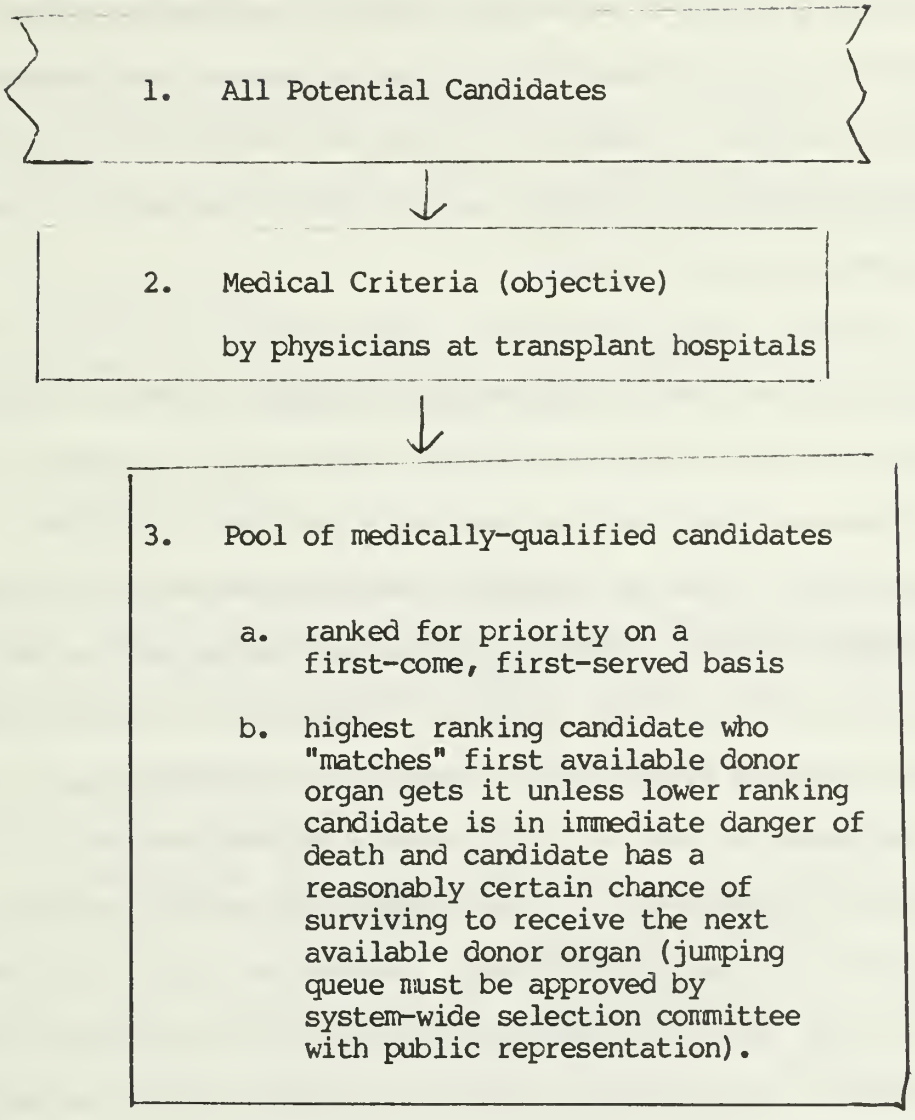
At present in Massachusetts there is no shortage of hospital space or surgical teams to perform transplants. Nevertheless, it is possible that at some time in the future there will develop a "pool" of acceptable candidates and that choices will have to be made among members of this pool as to who gets the next available, suitable organ. It is here that we must make a choice between using a conscious, value-laden, social worth selection criteria (including a committee to make the actual choice), or some type of random device. In view of the unacceptability and arbitrariness of social worth criteria being applied, implicitly or explicitly, by committee, the

Task Force does not believe such a process is viable or proper. On the other hand, strict adherence to a lottery might create a situation where an individual who has only a one in four chance of living five years with a transplant (but who could survive another six months without one) would get an organ before an individual who could survive as long or longer, but who will die within days or hours if he or she is not immediately transplanted. Accordingly, we believe the most reasonable approach would be to generally allocate organs on a first-come, first-served basis to members of the pool, with individuals being able to "jump" the queue if the second level selection committee believes they are in immediate danger of death and the person who would otherwise get the organ can survive long enough to be reasonably assured that he or she will be able to get another organ.

We adopt the first-come, first served method of basic selection (after a medical screen) because it most closely approximates the randomness of a straight lottery, without having obviousness of making equity the only value being promoted. Some unfairness is introduced by the fact that the more wealthy and medically-astute will likely get into the pool first, and thus be ahead in line, but this advantage should decrease sharply as public awareness of the program grows. The possibility of unfairness is also inherent in permitting individuals to jump the queue, but the necessity for approval by a committee with significant public representation on it decreases the likelihood of medical favoritism and such an exception seems reasonable to protect our view of the value of life. (See Table 1)

Table 1

Screening Procedure


1. All Potential Candidates
2. Medical Criteria (objective)
by physicians at transplant hospitals
3. Pool of medically-qualified candidates
a. ranked for priority on a first-come, first-served basis
b. highest ranking candidate who "matches" first available donor organ gets it unless lower ranking candidate is in immediate danger of death and candidate has a reasonably certain chance of surviving to receive the next available donor organ (jumping queue must be approved by system-wide selection committee with public representation).

Society will have to face the reality that should the resources devoted to organ transplantation be limited (as they are now and are likely to be in the future), at some point it is likely that significant numbers of individuals will die in the "pool" waiting for a transplant. There are three things that can be done to avoid this: (1) medical criteria can be made stricter, perhaps by adding a more rigorous notion of "quality" of life to longevity and prospects for rehabilitation; (2) resources devoted to transplantation and organ procurement can be increased; or (3) individuals can be persuaded not to attempt to join the pool.

Of these three options, only number 3 has the promise of both conserving resources and promoting individual autonomy. While we assume that most persons medically eligible for a transplant would want one, we also assume at least some would not - at least if they understood all that was involved, including the need for a lifetime commitment to daily immunosuppression medications and periodic medical monitoring for rejection symptoms. Accordingly, it makes public policy sense to publicize the risks and side-effects of transplantation, and to require careful explanations of the procedure be given to prospective patients before they undergo medical screening. It may be that by the time patients come to the transplant center they have their minds made up and would do anything to get the transplant. Nonetheless, if there are patients who, when confronted with all the facts, would voluntarily elect not to proceed, we enhance both their own freedom and the efficiency and cost-effectiveness of the transplantation system by screening them out as early as possible.

Notes

1. Much of this section relies on ideas in or derived from the work of Professor Guido Calabresi of Yale Law School, especially from G. Calabresi & P. Bobbitt, Tragic Choices, Norton, NY 1978.

2. Fletcher, J. Our Shameful Waste of Human Tissue, in The Religious Situation, Cutler, DR, ed., Beacon Press, Boston, 1969, 223-252.

3. Quoted in Fox, R. & Swazey, J., The Courage to Fail, U. of Chicago Press, Chicago, 1974 at 232.

4. Sanders & Dukeminier, Medical Advance and Legal Lag: Hemodialysis and Kidney Transplantation, 15 UCLA L. Rev. 357 (1968).

5. Rettig, R.A., The Policy Debate on Patient Care Financing for Victims of End Stage Renal Disease, 40 Law & Contemporary Problems 196 (1976).

6. See supra, note 1.

7. President's Commission for the Study of Ethical Problems in Medicine, Securing Access to Health Care, U.S. Gov. Print Office, 1983 at 25.

8. See supra, note 1.

9. Bayer, R., Justice and Health Care in an Era of Cost Containment: Allocating Scarce Medical Resources, Social Responsibility, 9:37-52, 1984. And see, Annas, G.J., Allocation of Artificial Hearts in the Year 2002: Minerva v. National Health Agency, 3 Am. J. Law & Medicine 59-76 (1977).

10. Commentary, UK's Poor Record in Treatment of Renal Failure, Lancet, July 7, 1984 at 53.

11. A 1969 study of the criteria employed by kidney dialysis centers in the United States found that the eight most frequently employed criteria were: 1. Willingness to cooperate in treatment regimen (86%); 2. medical suitability (79%); 3. absence of other disabling disease (69%); 4. intelligence, to understand treatment (34%); 5. liklihood of vocational rehabilitation (32%); 6. age (20%); 7. primacy of application for available vacancy (26%); and 8. psychiatric evaluation (25%). Fox & Swazey, supra, note 3 at 230. The family question, as put to candidates at Stanford's heart transplantation center has been, "Does the patient have a strong supportive family willing and able to withstand the apprehension, anxiety, fear, waiting, fatigue, separation, euphoria, disappointment, and grief that the different phases of cardiac transplantation entail? Does the family have enough strength to provide continuing support to the patient as well as to manage the stresses of cardiac transplantion themselves?" Id. at 310-311.

12. Most, but not all, liver transplant programs exclude active alcoholics from consideration for liver transplantation. The Boston Center for Liver Transplantation, for example excludes alcoholics who have not abstained for less than two years; and more generally excludes "active drug or alcohol" users. The Brigham and Women's Guidelines for Cardiac Transplantation are somewhat less explicit, asking referring physicians to consider "a history of alcohol or drug abuse, or mental illness that would complicate post-transplantation followup" as a "contraindication to cardiac transplantation." The Task Force concluded that blanket exclusions, like that of the Liver Center, are arbitrary and tend to reinforce negative and destructive societal stereotypes. Accordingly, such individuals should not be per se excluded from screening if they want a transplant. On the other hand, it is reasonable and proper to consider the impact of the patient's substance abuse or mental illness on the probability of successfully following an immunosuppression regimen and being physically rehabilitated following transplant. Although such a judgment will also have large subjective elements, it is here, rather than on the disease of substance abuse itself, that the decision should focus.

13. Evans, Roger, Health Care Technology and the Inevitability of Resource Allocation and Rationing Decisions, Part II, JAMA 249: 2208, 2217 (April 22/29, 1983).

14. Id.

15. The New England Organ Bank is in the process of changing their policy, but the following summarizes what it was. One of the two kidneys goes to the regional center that covers the hospital that procured it and the kidney is used at their discretion. The other is distributed on the basis of matching. Kidney matching is generally done on the basis of tissue compatibility to minimize the probability of rejection. Most importantly, the recipient must be crossmatch negative, i.e. there must not be a reaction when the recipient's blood is mixed with the white blood cells of the donor. If there is, there is likely to be a severe and early rejection of the kidney. If there is not, a patient in immediate need of a kidney may obtain one on this basis alone.

More sophisticated immunological tests are usually performed, however, so that the kidney can go to the matching individual with the lowest probability of ever obtaining a kidney. The quest is to determine the recipient's allergic status to foreign substances, like blood and kidneys. The more highly allergic a patient is, the more difficult it will be to find the patient a suitable kidney. Past blood transfusions increase the patient's allergic reaction status, as, of course, do prior transplants. The patient's allergic status is "panel reactivity" and is expressed as a percentage, with 100% being the most allergic. The panel reactivity is determined by the presence of antibodies to 160 antigens, common in North American man. The more blood used, the higher percentage of antibodies to the 160 antigens. 100% reactivity means that the patient has antibodies to all antigens.

Patients with high percentages get preference; if percentages are equal, the bank goes to the next two tissue matching tests:

HLA-DR matching and no incompatibility for HLA-A, B antigens. The patient scoring the highest match on these tests should receive the kidney. In the unlikely event that two or more patients still score the same, hospitals with the better record of organ procurement are given priority. And if no patient in the region scores well enough to justify transplantation, the organ is referred to a national pool. These general criteria were supplied by the New England Organ Bank, whose priorities for kidney distribution of the second kidney are 1) medically urgent; 2) sensitized patient, negative crossmatches; 50-100% panel reactivity for greater than 3 months; 3) full house HLA-DR match; 4) no incompatability for HLA-A, B antigens; 5) NEOB institutional net credit rating; and 6) export of kidney to National Network.

Distribution systems for livers and hearts are much less sophisticated. Patient blood type and age/weight factors are first priorities. Hearts are generally crossmatched, while livers are not. After these criteria are met, medical urgency is usually the primary priority. Because hearts and livers survive less than twelve hours (vs. 72 hours for kidneys) after removal from the donor, there are much stricter geographic and temporal constraints on distribution. See generally, Organ Transplants, Hearings before the Subcomm. on Investigations and Oversight, Comm. on Science & Technology, U.S. House of Representatives, April 13, 14, 27, 1983.

With artificial organs, cross-matching will no longer be an issue, and we will have to directly confront distribution of replacement organs on more exclusively non-medical terms. See, e.g., Annas supra note 9.

V. THE CONSORTIUM APPROACH TO ORGAN TRANSPLANTATION

Two alternatives face the Department of Public Health in granting a certificate of need for a program to do specific organ transplantation: begin with a single hospital site or begin with multiple sites. Economically there is no justification for departure from a single site until volume justifies it. On the other hand, a consortium approach can make less likely the necessity of expanding facilities at an individual site, or having to displace significant numbers of patients at a single site, if a significant number of procedures are performed. It can be advantageous in its own right if all the hospitals involved can deliver uniformily high quality of care, and they enter into a formal "cooperative agreement" to coordinate efforts, share facilities, and use uniform patient selection and treatment protocols so their results can be meaningfully assessed both collectively and comparatively.

If transplantation is begun at a single site, and if additional sites are later deemed desirable and needed, it is reasonable to require that there be formal cooperation between the original site and the additional sites to prevent duplication of effort, maximize exisiting expertise, and promote cooperation and system efficiency. The Massachusetts Department of Public Health has already decided to begin liver transplantation in a four-hospital "consortium", and heart transplantation in a single hospital. As these two models are assessed, and new consortium arrangments are proposed, it becomes critical to responsible policy development that the characteristics of a "worthwhile consortium" be outlined. This is the purpose of this section of the Task Force Report.

What Makes A Worthwhile Transplant Consortium?

The case for a consortium among hospitals to do organ transplants is twofold. First is the contention that by dividing cases among institutions we can insure that all the available capacity is utilized to serve the area's patient load without having to undertake new, costly capital construction. Second, consortium advocates insist that despite the dispersal of patients involved, such arrangements can improve teaching, learning, and patient care by facilitating the pooling of knowledge and experience among institutions and their professional staffs.

Skeptics of the consortium idea, on the other hand, worry that it is simply a strategy to avoid and undermine the DON process, and that care will be inefficiently provided because personnel, facilities, and services will be needlessly duplicated and hence under-utilized. Dividing a small patient cohort among surgical and patient care teams could also prevent the development of the highest possible level of experience and expertise in one of those teams, with adverse results for quality of care. Multiple sites may also undermine the goal of the certificate of need laws by actually promoting duplication and inefficiency. Finally, there is concern that once multiple institutions become involved, their individual efforts to build up the size and prestige of their separate programs competitively will lead to inappropriate expansion in the amount of service performed, and in the amount of resources consumed.

The challenge of devising a "worthwhile" transplant consortium

is to achieve the potentially desirable gains while avoiding conceivable adverse results. In short, the Department should be sure it is dealing with a real consortium, and not just one used simply as a pretext to gain a certificate of need. A worthwhile consortium must be more than an excuse for uncooperative competition, or a method to create exclusionary cartel by the nomminally affiliated organizations. If a worthwhile consortium cannot be developed, transplantation should be begun at a single site and no other sites approved without a demonstration of public need. Institutional desire to perform prestigious procedures is an insufficient justification for a consortium.

A worthwhile consortium should come as close as possible to being a single, integrated medical service, rationally and efficiently utilizing the various talents, facilities and equipment available to it at the participating institutions.

Each member of a worthwhile consortium must be able to demonstrate independently either its ability to perform the transplant in question in a manner consistent with high quality of care (as evidenced by past experience with similar types of surgery, such as kidney transplantation), or in the event it does not perform the surgery, its ability to act in consort with the other members of the consortium in a particular aspect of transplantation, if the transplant operations themselves will not be performed at the particular hospital.

General guidelines, such as those proposed by the Liver Transplantation Task Force, should serve as minimum membership

requirements in any state-sanctioned consortium. In the only other state to implement an organ transplant consortium (announced July 3, 1984), Ohio, membership is limited to hospitals with an existing renal transplantation program that performs at least 50 kidney transplants annually, is a tertiary referral center, supports graduate medical education and research programs, and demonstrates a 24 hour a day institutional commitment to transplantation. Minimal competence requirements should apply to all consortium members actually performing transplants, but not to those engaged in related activities.

A worthwhile consortium will agree to develop, modify and use of a single set of patient selection and treatment protocols. The consortium should provide as nearly as possible the same care to all patients, without regard to which participating institution they are admitted. This requires common protocols for the selection of patients, operative procedures, post operative care, etc. The most reasonable mechanism would be to require the consortium to establish a system wide Review Committee that would have significant public representation as well as Department representation, to review and approve a common set of clinical protocols, selection criteria, consent procedures, organ procurement and distribution procedures, and confidentiality guidelines. The requirement to cooperate in the development of such common protocols will also help insure effective information exchange among cooperating personnel and institutions. This need is not limited to the surgical procedures themselves. It is equally

important in areas such as diagnosing and treating transplant rejection, treating infections due to immunosuppression, providing aftercare support, etc. Mechanisms must insure that skills and capacities in such areas developed at one institution are utilized by and transferred to other institutions in the consortium.

A worthwhile consortium will agree to treat all patients as a single clinical service and to joint publication of all research results. If the previous step is taken, it will be possible to treat all the patients, in all the participating hospitals, as part of a single clinical service for research and publication purposes. This will have value to society in that it would help avoid the problem of small sample sizes that would otherwise plague the individual institutions. It will also help insure growing cooperation among all physicians, nurses, researchers and institutions involved. This should help prevent the development of inter-institutional rivalry, give all an interest in the success of each, and foster genuine intellectual collaboartion. There should accordingly be an initial agreement on plans for periodic release and publication of results. This agreement should be planned so that broad clinical data are published jointly, and that no separate papers on patient series at individual member hospitals are published, with the possible exception of pediatric experience. There should, however, be adequate flexibility and opportunity for each of the hospitals or separate services within the hospitals to carry on and publish special studies or particular analyses so long as these are approved by the consortium and the knowledge

shared. For example, a pathologist at one hospital could write and publish a paper about one or two slides relating to a particular transplant without full consortium approval or participation - but this should be the exception.

A worthwhile consortium will use a common pool of potential recipients and a common procurment activity so that the allocation of organs among recipients is on an institutionally neutral or "blind" basis. While the New England Organ Bank provides some of this service, the plans and administrative arrangements of the consortium should insure that the probability that a given patient will receive a given organ is totally independent of the institution he or she happens to be a patient in. Thus there should be a commitment to treating all organs and all patients within the consortium as a fully common pool, with matching done on a medical basis without regard to the source of the organ, which institution's "turn" it was, etc. In this regard there should be a unified patient selection committee for the entire consortium.* Patients who pass an initial medical screening test at an individual member hospital would be referred to the consortium-wide committee for prioritization on the basis of medical urgency, organ match, and other patient selection criteria. This committee would be made up of representatives from each member institution, as well as representatives of the Department of Public Health and significant representation from the public-at-large. Selection

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*See Section IV, Patient Selection and Rationing Schemes, for a fuller discussion.

criteria and prioritization criteria must be public and filed with the Department of Public Health. If a patient has a preference for a particular hospital, every reasonable effort should be made to accomodate this preference.

A worthwhile consortium will have a formal program for the interchange and common use of staff and students. To prevent the development of distinct, unshared treatment techniques or care practices, the institutions should establish formal procedures for the exchange and interchange of staff (both physicians and others) and students (especially residents). This will keep all members of each team fully aware of what other institutions are learning and doing. Given the subtle variations on practice and skill that can easily develop, despite common formal treatment protocols, such mixing of personnel is needed to insure effective mutual learning and information transfer apart from desirable patient care results, such measures could also reduce costs (e.g. use of a single joint "on call" or nursing surgical team or organ procurement surgical team would be obviously cost saving). It is inefficient and unnecessary to pay every night to have two or three different sets of people standing by, one at each institution, when at most one will be needed. At the same time cross visitation by individuals is encouraged, it would seem inadvisable, if a patient is moved from one hospital to another, for the entire surgical team to transfer and operate in a strange hospital. Shared knowledge and experience should make any mandatoy rotation of surgeons unnecessary.

A worthwhile consortium will have a common training program. Consortium institutions should also develop a single post-graduate training program for each of the various surgical and medical specialties involved in the transplantation program. There is no cost or quality justification for limiting surgical residents, immunological residents, or other trainees, to education in a single program when better training, more information exchange and more experience for the trainees could be provided by a joint inter-hospital activity within each specialty.

A worthwhile consortium will agree to the efficient joint use of facilities and equipment. In order to avoid duplication, and achieve economies of scale, a worthwhile consortium will make efficient use of all equipment and facilities that can be effectively shared. For example, it may be that some equipment (e.g., "blood saver") can be shared among transplant programs. Furthermore, there may be some laboratory work which is expensive and time consuming, particularly in set up costs (Monitoring blood levels of cyclosporin appears to be one such task). In such cases, having one hospital laboratory do the work for all, seems sensible. Rotating the responsibility on a weekly or monthly basis for doing certain work, where they are consistent with maintaining both low costs and high quality, would be a possible alternative, but would be pointless duplication if its only justification was to give an institution "an equal chance." It is essential that a consortium proposal identify all areas where such savings could be made, and provide specific plans and propose

commitments to achieve such cooperation or specify why such cooperation is not possible.

A worthwhile consortium will utilize common format for data collection and a central staff and file. The records and publication activities of the consortium require not only joint protocols, but joint data collection. The existence of such a set of forms and records should be one of the conditions of consortium approval. This is true for both administrative and cost information as well as clinical information. Establishing the format, we should note, may be no easy task given inter-hospital variations in accounting and control systems.

Uniform data collection is a necessary precondition for approval of a consortium arrangement, but it is not a sufficient justification for one, since a single hospital would, by definition, achieve uniformity. Also, the Department could impose uniform data gathering on multiple hospitals even in the absence of a consortium agreement.

We believe a worthwhile consortium would require not only the use of identical forms for records, but also lead to the establishment of a physically distinct central records and administrative center as volume justifies it. There the records of all patients who have applied for a transplant (through any of the constituent institutions) could be kept, a single pool of candidates maintained, decisions on matching organs to patients coordinated, and a base provided for tracking recipients, conducting follow-up research, and performing other tasks.

Attention must, of course, be paid to Massachusetts laws regarding patient records, as well as general principles of confidentiality. The existence of a distinct physical home, however modest, would help insure the consortium's growth as an organizational entity.

A worthwhile Consortium will have a formal organization. A worthwhile consortium requires an identifiable locus of coordination. Each hospital involved should appoint senior persons as members of this Consortium, including one member from the Trustee/Administration group, a senior surgeon or physician with major ongoing responsibility in the field, and one or two people who will be collaborating in the work.

This group, comprising the representatives from various hospitals, should nominate a secretary who will arrange the meetings, maintain the notes and records, and whose budgetary requirements should be met jointly by the hospitals involved. The New England Organ Bank should have at least one representative.

Exclusivity will naturally arouse complaints and antagonisms from hospitals that are initally not members of the consortium since it is a traditional "cartel" arrangement. This problem should be clearly discerned, both in terms of total hospital load, and in "staging expansion" over the course of several years. If a hospital, not a member of such a consortium, has staff who would like to participate, they must be permitted (and hopefully encouraged) to attend the rounds and meetings with the consortium. If numbers of patients justify expansion, and the plans of the Commonwealth and reimbursement mechanisms allow, additional institutional participation should be made possible.

VI. RELIGIOUS VIEWS ON ORGAN TRANSPLANTS

Protestant Christian Perspectives*

No one can write with authority for Protestant Christianity as a whole, because of two facts: first, the multiple diversity of traditions and denominations; second, the lack of a single teaching authority. The best one can do is to characterize the common basis and style of ethical theory and decision making among the many Protestant churches as these may apply to organ transplantation.

Characteristically, Protestants look first to the Bible, especially to the life and teaching of Jesus, for knowledge and guidance. They read the Bible in the light of Christian history, particularly shaped by the reformers and teachers since the sixteenth century. Four Biblical doctrines stand out as relevant to organ transplantation.

1. Each human being is created by God as an integrated unity of body, soul, mind and spirit. The common notion that Christianity is concerned only with spiritual life and not with the health of the whole person is an unwarranted distortion. One's body is a "temple of the Holy Spirit" and a "member of Christ," wrote St. Paul; so the body is for the purpose of glorifying God. (First Letter to Corinthians 6:15, 19, 20).

*The Task Force is indebted to the generosity of Professor J. Robert Nelson of the Boston University School of Theology for preparing this section on the Protestant views.

2. Jesus himself was best known as a divinely empowered healer of all manner of diseases. Even as an acknowledged Jewish rabbi, he put healing ahead of Sabbath law (Gospel of Luke 6:9), and he commissioned his diciples to do everything possible to heal people.

3. Since the divine power of life itself was at Jesus' disposal, he willed only the health and fulfillment of life for people: that is, life in all its fullness for all people. As the most inclusive world body of Christian churches, the World Council of Churches, declared in its theme for 1983, "Jesus Christ [is] the Life of the World."

4. And yet, in the last analysis, said Jesus, it is one's righteousness - the good, obedient, purposeful, loving will - which is more important than physical, bodily wellbeing. In vigorous words he said, "It is better that you lose one of your members that your whole body be thrown into hell." (Gospel of Matthew 5:29).

Protestant Christians in general do not reject techniques of organ transplantation because these appear to violate the natural integrity of the body. Nevertheless, the whole body and its parts deserve full respect just because the body is indispensable to the whole person. Moreover, it is not in general believed that following the event of death the expected resurrection of the body will be a reconstituting of bone, flesh and blood. So neither living organ donation nor cadaver donation is proscribed by this religious belief.

The central Christian doctrine of self-giving love clearly warrants the donating of organs for the therapy of another person. No greater expression of love is there than to deny oneself, even to death, for the sake of another, and this without thought or desire for any reward for oneself. To give one's body without love is of no spiritual or heavenly benefit (First Letter to Corinthians 12:3). Much less would there be benefit in selling one's organs.

The high valuation of each human life as sacred before God means, also, that each person's integrity and free decision must be respected. Given appropriate circumstances, each one should have sole authority to determine the disposition of organs and body, whether as living or dead.

As for the broad and perplexing social and economic problems which are created by the increasing use of transplant therapy, Protestant Christians would urge that resolutions be sought only on the firm platform of opportunity and equitable treatment for as many persons as available resources allow.

The Roman Catholic Perspectives

The Roman Catholic Church approves and encourages organ transplants with certain moral parameters.

Regarding inter vivos transplants, the Ethical and Religious Directives for Catholic Health Facilities issued by the United States Bishops declare:

> The transplantation of organs from living donors is morally permissible when the anticipated benefit to the recipient is proportionate to the harm done to the donor, provided that the loss of such organ(s) does not deprive the donor of life itself nor of the functional integrity of his body. (United States Catholic Conference, Washington, D.C., 1971)

The moral justification for this directive is, according to the highly respected moralist, Gerald Kelly, S.J., ". . . the law of charity, which is based on the natural and supernatural unity of mankind according to which one's neighbor is `another self.' "(Cf. Theological Studies, September 1955, pp. 373 - 396)

This law of charity - which calls for the love of God through the love of neighbor - is likewise seen by Pope Pius XII as justifying the donation of organs from a cadaver. As pope from 1939 to 1958, he reflected upon numerous medico-moral problems, and his teaching is relied upon today by Pope John Paul II.

Pius XII held that once death was established according to criteria accepted by the medical profession, organs could morally be removed for use by another provided that two conditions are met. The first of these is that the cadaver, because it was previously an essential constituent of a human person, be treated with respect. The

second is that consent be obtained from the deceased before his death, or from those having the right to act for him after his death. Unless there were special circumstances, the Pope felt that the liberty and spontaneity of these parties involved had to be respected. At the same time, he saw the question of compensation as still lacking a definitive answer:

> Moreover, must one, as is often done, refuse on principle all compensation? This question remains unanswered. It cannot be doubted that grave abuses could occur if payment is demanded. But it would be going too far to declare immoral every acceptance or every demand of payment. The case is similar to blood transfusions. It is commendable for the donor to refuse recompense: it is not necessarily a fault to accept it. (Cf. Papal Teachings: The Human Body, St. Paul Editions, Boston, 1960, p. 381)

In addition, while Pope Pius XII taught that the poor as well as the rich were entitled to have taken into account their delicate human feelings for the bodies of their deceased, he also urged that all of society should be brought to evaluate these feelings in the light of a greater charity:

> On the other hand the public must be educated. It must be explained with intelligence and respect that to consent explicitly or tacitly to serious damage to the integrity of the corpse in the interest of those who are suffering is no violation of the reverence due to the dead since it is justified by valid reasons. In spite of everything, this consent can involve sadness and sacrifice for the near relatives, but this sacrifice is glorified by the aureole of merciful charity toward some suffering brothers. (Cf. Op. Cit., p. 382)

Finally, the Roman Catholic Church would see the virtue of distributive justice as very relevant to the present discussion of organ transplants. This virtue calls for government to apportion fairly benefits and burdens among its citizens. In so far as the demands of the common good involve the government in the financing and regulating of organ transplants, there is a corresponding moral obligation of equitable distribution of costs and access.

Jewish Attitudes

The infinite value of all human beings is a central and unequivocal principle in Judaism. To save a single life is regarded as if one has saved the entire world. Almost all ritual requirements may be suspended in the face of any danger to life. The duty to heal the sick is seen as a religious imperative.

Consonant with this supreme value, most rabbinic authorities affirm that organ transplants which serve to perpetuate life are permitted.

Transplant procedures in which the organ is taken from a dead donor must follow these guidelines:

1. Nothing shall be done to prepare the critically ill donor for transplantation surgery if this procedure hastens death in any way.

2. Under Jewish Law, death is determined by cessation of all spontaneous respiratory and circulatory activities for a sufficiently long period of time to make resuscitation medically impossible.[1] Conservative and reform rabbinic authorities will more readily accept "brain death" criteria.[2]

3. Realizing the complexity of issues surrounding the determination of the "time of death," the practice of assigning such judgments to a team of physicians not involved in the transplantation procedures is recommended.

4. Consent of the patient or next of kin should be secured before transplantation procedures are initiated.

5. While it is generally agreed that the use of an organ from a dead donor to provide life for another human being permits, and even urges, the suspension of laws regarding desecration of the dead, every measure should be maintained to respect the dignity of the body and its burial in accordance with Jewish Law and practice.

It is permitted, but not obligatory, for a donor to endanger his life or health to supply an organ to a recipient whose life would be saved by this act. Certainly this is the case where the probability of saving the life of the recipient is substantially greater than the risk to the donor's life or health. A small risk may be taken by the donor if the chances for success in the recipient are substantial; a major risk may be undertaken if otherwise the death of the recipient is certain.

Advancements in new medical technologies have raised a series of new ethical questions centering on the distribution of finite resources. Who shall decide how to allocate these limited resources? What patient selection criteria will be employed? Will "social value" criteria emerge in which some authorities determine who is less or more valuable for society's future.

These questions, new and challenging, require thoughtful, ongoing discussion. Here is a statement of one group of rabbinic leaders, representing a broad spectrum of the Jewish religious community:

We view with particular disfavor the use of a social-value index as a criterion for assignment of scarce medical resources. It raises the spectre of racism, elitism and eugenic considerations, and poses a threat to the foundations of a democratic society as well as to the concept of infinite human worth.

In an inescapable situation of scarcity of medical resources, it may be morally justifiable to establish a criterion of inclusion, even if thereby some potential patients are denied medical treatment altogether. The patient facing imminent death with therapeutic hope may be excluded, but the decision not to initiate invasive medical procedures for a terminal patient is independent of the issue of scarcity. Even with ample medical resources, the medical procedures which are not acts of `healing' have no warrant either as clinical procedures or moral acts.

Just as inclusion or exclusion on the basis of the patient's social value is unacceptable, so is it unacceptable to distinguish among patients with real therapeutic hope on the basis of their varying potential for recovery. This is the foundation for the practice of triage, and is fundamentally incompatable with Jewish values and Jewish Law. Since, in Judaism, all human life is equally sacred, including each moment of an individual's life... therefore, no selection is justifiable among those with the need for and the possibility, however slim, of cure. Only two choices thus present themselves to a physician or hospital administrator...the first would be to treat, fully and completely, the first patient on the list who needed treatment, and then treat the next patient on the list if resources permitted. The second option would be a random chance lottery to allocate treatment to the few as far as it goes.[3]

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1. Compendium on Medical Ethics, Rabbi Dr. David M. Feldman and Fred Rosner, M.D. editors, Federation of Jewish Philanthropies of New York, 1984, p. 87.

2. Judaism Confronts Contemporary Issues, Alex J. Goldman, Shengold Publishers, Inc., New York, 1978, p. 229 ft.

3. Compendium on Medical Ethics, supra note 1, p. 104-106.

VII. REIMBURSEMENT POLICIES FOR ORGAN TRANSPLANTATION

Faced with rapid advances in technology and increasing costs, health planners, regulators and third party payors are being challenged to develop new policies and programs for payment of organ transplantation. This section describes the policies of the Federal Government, Medicare, State Medicaid programs, Blue Cross/Blue Shield, commercial insurers and policies in some other countries.

Federal Policy

With the exception of kidney transplants funded by the End Stage Renal Disease (ESRD) program of Medicare, there is no federal policy on organ transplantation. The Medicare program is administered by the Health Care Financing Administration (HCFA), a division of the Department of Health and Human Services (HHS), which determines procedures covered and appropriate levels of reimbursement. Medicare has labelled heart and liver transplants as experimental and has thus not authorized payment for these procedures. However, transplantation is moving rapidly from the realm of human experimentation to therapy, and new criteria for reimbursement are emerging. In 1980, Patricia Robert Harris, Secretary of HHS, announced that new technologies must be evaluated not only on the traditional bases of safety and efficacy, but also on cost-effectiveness and long range social, economic and ethical considerations. At a press conference on June 12, 1980, Secretary Harris stated:

> A final decision on coverage of heart transplants under Medicare, whatever that decision shall be, must be fully justified by a clear and careful analysis of all pertinent facts about which the public is fully informed. Heart transplantation illustrates the complex policy issues

> presented by rapidly advancing medical technologies and procedures. It is incumbent on all of us-the government, the medical profession, and the public-to assess carefully the safety, efficacy and the social consequences of new procedures before financing their wide dissemination. I fully expect that studies of the sort we propose for heart transplantation will become increasingly necessary in the years ahead.

In November 1979 HCFA authorized Medicare payment for heart transplants at Stanford University Medical Center. Payment, which was authorized temporarily pending development of final criteria for coverage, was discontinued effective June 13, 1980 due to lack of sufficient information concerning a patient selection process, long term social, economic, and ethical consequences of the procedure, and the potential for national expansion of the transplant procedure. Several months later the Medicare Program solicited hospitals and medical centers to participate in a study of heart transplants. The study was to include all aspects of heart transplants including scientific, social, economic and ethical issues. This $1.5 million study was submitted to HCFA by the Battelle Center in Seattle in September 1984, and is scheduled for public release in early 1985. The hospitals which performed transplants in the study were Stanford University, Medical College of Virginia and Richmond Veterans Administration Hospital, Richmond, Va., Columbia-Presbyterian in New York and the Universities of Minnesota, Pittsburgh, and Arizona.

The Office of Health Technology Assessment, a division of the National Center for Health Services Research, has been asked by HCFA to evaluate the safety and effectiveness of heart, pancreas and liver transplantation. Assessment of liver transplant requested by HCFA in

August 1982, was finished in 1983. The report concluded that liver transplantation was technically feasible, extremely expensive and a very complicated operation capable of extending the lives of carefully selected patients with end stage liver disease. The report went on, however, to raise questions about selection mechanisms, organ availability, costs, institutional capabilities, and equality of access.

Based on this report, HHS announced that at this time the Administration supports federal recognition of liver transplantation as non-experimental for children with biliary atresia and other rare congenital abnormalities. It has been reported that the Department of Defense will issue regulations for its CHAMPUS program permitting reimbursement for liver transplantation. Some transplants are financed by federal health research funds through the National Institute of Health. NIH is financing heart transplants at Stanford and will continue until 1987. Other federal agencies funding heart transplants include the Veterans Administration's program at Richmond, Virginia.

Medicare

The Medicare program is one of a number of programs administered by the Health Care Financing Administration (HCFA). Medicare benefits are available to those 65 or over, those who are disabled, and those who are suffering from End-Stage Renal Disease (ESRD). HCFA determines the procedures covered and the appropriate level of reimbursement.

Presently the only major organ transplants covered by Medicare are kidney transplants. Renal transplants and dialysis were included in the Medicare program under section 2991 of Public Law 92-603, effective October 30, 1972. This program has been successful from the point of view of improving access and providing health care to those suffering from ESRD, and has grown rapidly since 1972. The number of beneficiaries has risen from 10,000 in 1974 to more than 65,000 in 1982; while the annual cost rose from $242 million in 1974 to almost $2 billion in 1982, and a projected $5.5 billion for 90,000 patients in 1995.

A number of commentators have noted the disproportionate share of Medicare funds spent for ESRD recipients. For example, in 1980, ESRD beneficiaries were less than 1/2 of 1% of total beneficiaries for Supplementary Medical Insurance (professional and ancillary services); but ESRD costs represented five percent of the total Medicare budget for these services. Another high figure for kidney program is the dialysis rate. The United States provides dialysis for patients at a rate which far exceeds that of Europe and Israel. The U.S. dialysis rate is 204.7 per million. Of the countries studied, Israel has the next highest rate (144 per million) and France (123 per million) has the highest rate in Western Europe. The dialysis rate in the United Kingdom is 52 per million. Among the states in the U.S. the highest is the District of Columbia (983 per million) and the lowest is Wyoming (20 per million).

Medicaid

Medicare policy on acceptable procedures strongly affects policies of many states in the establishment and implementation of Medicaid standards. The Medicaid program is a federal/state program. While states are required to pay for a basic set of acute, out-patient and skilled nursing home services, other optional services can be added to the state program under the same federal-state cost sharing arrangements. Several groups of clients are covered by Medicaid, including the elderly, dependent children and their families, and the disabled. Also covered by many states are those who have spent a portion of their income on medical care or have "spent-down" and have become "medically indigent."

The federal government will not fund heart and liver transplants through Medicare, but will pay the federal portion of Medicaid transplant coverage in states which choose to fund them. To learn more about Medicaid funded transplants, the Task Force carried out an informal survey of eleven states, including the contiguous New England states (Connecticut, Rhode Island, Vermont, New Hampshire), and states in other regions (Arizona, California, Maryland, Michigan, New Jersey, New York, and Pennsylvania). Medicaid central offices in these states were asked if they had received any requests for liver, heart or heart/lung transplants, if requests had been approved and if a prior authorization mechaninism or case-management technique was used for these requests. If the respondent mentioned the Medicare criteria as part of explanation or rationale for state policy, this was also noted.

Nine of the eleven states had at least one request, and eight had approved at least one transplant. All three states receiving requests but not granting approvals cited the Medicare criteria in explaining their decision. Seven states had approved at least one liver transplant, five states had approved at least one heart transplant and four states had approved at least one heart-lung transplant. All states but one which had approved at least one transplant had a prior authorization mechanism. This is not unusual because for many Medicaid eligible patients, organ transplantation will be an out-of-state service which automatically requires prior authorization. Several states emphasized that recent transplants were exceptions and were not established state policy. Other states reported that transplants were the subject of ongoing discussion or that reimbursement arrangements for transplant limited the hospitals to the standard per diem rate for the stay. In another state, liver transplants were being approved for bilary atresia only. Finally Medicaid may not be the only state program capable of covering transplantation. One state reported that two residents turned down by Medicaid received a transplant through the vocational rehabilitation agency in the state. The Department of Welfare in this state paid for the hospitalization and related costs.

Medicaid-New England States

Of five other New England states, only Vermont at present has received no transplant requests. Two states, Maine and Connecticut, have authorized transplants. Maine has authorized a heart transplant,

Connecticut has authorized a heart/lung transplant and three heart transplants. All New England states contacted have staff working on transplant issues.

Medicaid-Massachusetts

The Medicaid program in Massachusetts will pay for heart, heart-lung, and liver transplants for eligible patients. Potential recipients must meet both federally-established Medicaid financial eligibility criteria, and medical criteria developed by the Massachusetts Medicaid Review Committee to determine medical necessity. Financial eligibility criteria include provision for those who have "spent-down" by spending their income on medical expenses. Medicaid is the payor of last resort on these procedures. All available resources will be applied to the cost of the procedure before Medicaid contributes.

Medical criteria for each type of transplant define the medical conditions and circumstances for which the procedure is appropriate. Examples of these standards are age criteria, clinical diagnosis, and the presence of specific clinical signs. Based on the criteria, the Medical Review Committee, a physician advisory group representing a number of medical specialties, makes case-by-case determinations of appropriateness. To allow time for the prior authorization procedures, requests for approval should be made 14 days prior to the need for surgery. In a medical emergency, review of the material can be completed by central office staff within 2 days.

The Massachusetts Medicaid program has paid for several

out-of-state transplants in the past, and following the implementation of organ transplant in-state, has approved payment for several in-state recipients.

National Blue Cross and Blue Shield Policy

Currently, the policies of "the Blues" vary by state. The plans closest to the major transplant centers have been compelled to address the issue to a greater extent than the outlying plans. Although a few plans have tried to provide coverage through innovative methods, several have taken the position of addressing each transplant request on an individual consideration basis. In a number of plans, no requests have been made to cover such services and, therefore, the need for a specific policy statement has not been forced.

Twenty plans have formal policies to pay for one or more of the types of transplants. All twenty plans cover liver transplants. Nineteen cover heart transplants as well. At least one of the twenty covers all organ transplants. Ten additional plans have paid for one or more cases based on an administrative decision, and ten plans have specifically denied claims. Many plans have exclusions in their contracts for experimental/investigational procedures.

Among the New England states, the policy varies widely:

1. Blue Cross and Blue Shield of Rhode Island is offering a rider to its current contracts which would cover all investigational transplant procedures. They recognize heart, liver, heart-lung, pancreas, and small intestine transplants as coverable.

2. Blue Cross of Vermont, Blue Cross/Blue Shield of New Hampshire and Blue Cross/Blue Shield of Maine have had a limited number of requests for coverage. The number of subscribers in these plans has been too small to underwrite such expensive surgery and the plans are looking

for ways to put coverage in place without excessive cost. A suggestion under discussion in Vermont is a statewide insurance pool to share the risks. Blue Cross/Blue Shield of New Hampshire will cover liver, heart, heart/lung and pancreas transplants as of June 1, 1984. Blue Cross/Blue Shield of Maine has obtained re-insurance for transplant and expects to offer coverage as of January 1985.

3. Blue Cross/Blue Shield of Connecticut provides coverage for heart, liver and heart-lung transplants and has paid for several transplants. They are presently completing a study which will assist them in developing a more complete transplant policy.

Most plans, whether or not they have developed a policy, are experiencing frustration in attempting to address the issue on a local level. Issues such as clinical indications for the various types of transplants, viable funding mechanisms, the optimal number of transplant centers, and the criteria for their certification, remain unanswered.

Blue Cross/Blue Shield in Massachusetts

Blue Cross and Blue Shield of Massachusetts provide coverage for medical procedures which are considered "generally accepted." The Corporations rely on the advice of the Interspecialty Medical Advisory Committee (IMAC) for determination of which procedures meet the established criteria for general acceptability.

Established in 1941 to advise the Board of Directors on medical issues, IMAC is comprised of 38 professional physician and paramedical members, representing over 26 medical and surgical specialties. Sub-committees for each specialty provide IMAC with an advisory resource of over 300 medical and paramedical professionals throughout the state.

Decisions of IMAC do not in and of themselves constitute Blue Cross and Blue Shield policy changes. The Central Professional Service Committee (CPSC), a bylaw committee of the Blue Shield Board of Directors, must approve IMAC recommendations for conformity to "Generally Accepted Guidelines" established for surgical and medical procedures. A generally accepted surgical or medical procedure is defined as a procedure which:

a. has completed the research or experimental stage of development;

b. does not involve, as an integral part of the procedure, the use of any drug, substance, or device which has not been released by the Food and Drug Administration or other governmental licensing agencies for general use by qualified physicians;

c. is in general use for patient care by physicians qualified to perform the procedure;

d. is of demonstrated value for the diagnosis or treatment of an illness, injury, or bodily function.

Using these review procedures, the Corporations approved corneal transplants in the 1950s, kidney transplants in the 1960s and, in 1980, certain bone marrow transplants. Heart transplants were first reviewed by IMAC in 1977 and liver transplants were considered in 1978. At that time IMAC recommended and CPSC concurred, that neither procedure met the criteria for "generally accepted." Liver transplants had another review in September and November, 1982, but IMAC voted in November that it was not a generally accepted procedure. This recommendation was upheld by CPSC in February, 1983. Then, in July, 1983, IMAC reviewed heart transplantation and the following vote to defer final approval of heart transplants was taken:

> Motion was made and seconded that the procedure, Heart Transplantation, <u>appears</u> to be a generally accepted procedure.

However, because the procedure requires the use of a non FDA approved drug, Cyclosporine A, the Committee recommends deferral of final approval at the present time. (20 yeas, 4 nays, 1 abstention.)

Cyclosporine A received FDA approval on November 14, 1983. Liver, heart and heart-lung transplants were considered again by IMAC in January, 1984, and by CPSC in February, 1984. Both groups voted that these three transplants were now generally accepted.

In response to public pressure, in August of 1983, Blue Cross and Blue Shield of Massachusetts announced a program for insuring the costs of liver, heart and heart-lung transplants, called the Transplant Insurance Program (TIP). It was a stand-alone program that provided its own level of benefits, rather than adding to existing basic Blue Cross and Blue Shield coverage.

Current Policy

Massachusetts Blue Cross and Blue Shield as of Febraury 1, 1984, will pay for heart, liver and heart-lung transplants as part of the regular benefit package rather than under the Transplant Insurance Plan. The coverage will cost $24 a year for a family, about $10 million total. This is about one percent of the average statewide family premium. In 1986 the cost will increase to $35.4 million. The Transplant Insurance Plan will continue to be offered by Blue Cross and Blue Shield and may be attractive to small employee groups since it is "community-rated" rather than "experience-rated" and thus more favorably priced.

Commercial Insurance

Over three-fourths of the 30 major commercial health insurers will pay for heart or liver tranplants under their group major medical health plans. An informal survey prepared by the Health Insurance Association of America in June of 1983 showed that 82% of the companies were willing to pay for liver transplants and 85% were willing to pay for heart transplants. In covering these procedures, reimbursement by many insurance companies will depend on compliance with certain criteria. Examples of conditions and questions asked by many carriers include:

- Is the procedure medically necessary?
- Have all other conventional methods of treatment been tried?
- Is the patient's condition life-threatening?
- Is the procedure safe and effective?
- Has the policy holder requested coverage for this procedure?

In addition, some policy holders have contracts which specifically exclude certain procedures.

New medical procedures are reimbursed by commercial insurers after a study of safety and effectiveness. Sources of information used by insurance companies include the medical profession, specialty medical associations, state or national medical societies, new research studies, articles in medical journals and government reports. If the procedure is controversial or has not been proven safe and effective, a company may decide against reimbursement. Officials of HIAA say an industry-wide decision to cover transplants could come within one year.

Representative Policies from other Countries

Sweden

Heart and liver transplants are not done in Sweden, but Swedish citizens have received transplants in England. The procedures are approved individually, and are paid for by the Swedish County councils.

England

Heart, liver, and a limited number of heart/lung transplants are performed in England. One center for liver transplant and two for heart transplant, are funded by the National Health Service. The Health Service recently announced plans to provide a further year's support for the two heart transplant centers. This decision was based on the interim report of a research study group sponsored by the Department of Health and Social Security. The final report is due at the end of 1984.

Netherlands

Liver, but not heart transplants, are performed in Holland. Permission for establishment of the liver transplant center in Gronigen was granted by the government and financed with funds from private insurance companies.

Canada

Organ transplants in Canada are financed by the individual

provincial health plans and vary according to the comprehensive nature of each plan. Kidney transplants are routinely covered. Heart, liver and heart-lung transplants are considered more experimental and can be covered through prior authorization and special application to the Ministry of Health. Patients are referred at the recommendation of the attending physician and referrals may include out of province and United States locations. Heart and liver transplants are performed in London, Ontario and Montreal, Quebec.

APPENDIX

DEPARTMENT OF PUBLIC HEALTH

TASK FORCE ON ORGAN TRANSPLANTATION

Charge

The Task Force is charged with the development of standards and processes for evaluating the use of organ transplantation. The difficult issues facing the medical care sector and society as a whole will be discussed in terms of medical, economic, societal and ethical factors as they impact on the individual, on the family and on society.

The work of the Task Force can be categorized in terms of the when, who, what and how of organ transplant.

When

When should the procedure be generally available in Massachusetts and when should patients receive the procedure? Most medical interventions appear to have both an experimental and a therapeutic phase which reflect not only differing survival rates but also clinical judgements and FDA approvals. Should transplants be available in the state while experimental or only when declared therapeutic? In addition, patients can be transplanted at many points in their illness; for example in the last one year of life or the last six months. Transplantation has been generally regarded as a measure of last resort to be used as late as possible when there appears no hope of improvement but before the patient is too ill to recover from the procedure. Should these decisions address relief of pain or suffering and the poor quality of life experienced by the patient while awaiting transplant?

Who

Who is to receive the operation? Patients with the best chance of survival or those who are the sickest; different centers presently use different policies. Faced with limited resources should we transplant those with more years of life left, those who are successful in their chosen career, or those with most family responsibilities? Or should all have an equal chance under the concept of the sanctity of human life? The "who" question implies access and financial coverage but also involves referral patterns especially when the treatment is available at a limited number of centers.

What

What should be the result from the procedure? Should the patients experience a better quality of life, should they be returned to a productive life, should their pain be relieved? What are the avoided costs, the costs of conventional therapy? What methods should be used to calculate these costs and benefits in terms of direct and indirect medical care as well as in terms of the individual, the family and society.

How

How should these interventions be financed, how should resources be allocated and how should the decisions on when, who and what be made? Should coverage for transplantation be mandated? Is it a right? How should employers, and third-party payors be involved? Should coverage be provided by the federal government categorically as with End Stage Renal Disease? How should equality of access be assured? While the media have been helpful to many families in focusing attention on problems of donor procurement and financing, this is not the best mechanism for equality of access.

Access to transplantation is not solely an issue of limits on financial resources and insurance coverage but is also a function of the numbers of potential organs available for transplantation. How can donors and their families be safeguarded from potentially inopportune retrieval methods?

The question of financing is interwoven with that of resource allocation. What portion of the gross state product should go for medical care and how should that be apportioned? What priority should be placed on extreme and expensive medical interventions versus other programs, which while less expensive and less dramatic impact on a wider number of the Commonwealth's citizens? These programs, for example better dental health, nutrition and prevention, must compete for health care dollars with transplants. How should these decisions be made, by what group and under what mechanism? Within specific programs, for example, transplants, how should patients be selected and what should be the composition and the authority of these decision-making groups?

The Task Force will prepare recommendations on all of these questions - when, who, what and how and will recommend mechanisms and methods to implement their decisions where possible.

Composition and Structure

The composition of the advisory body will reflect a cross section of interested and informed citizens. The Task Force will be no larger than fifteen (15) members and will be geographically representative, if possible. The chairman and vice-chairman of the Task Force will be appointed by the Commissioner of Public Health. The following broad categories and, where possible, subcategories will be represented on the Task Force.

1. health professionals; physicians, nurses, others
2. legal experts; lawyers,
3. economists; health economists, social welfare economists
4. ethicists; academics, philosophers
5. clergy; priests, rabbis and ministers
6. business; media, executives, health benefits managers
7. labor; business managers, interested leaders
8. public: League of Women Voters, aged
9. consumers; transplant recipients or their families, patients
10. hospital officials; administrators, trustees
11. elected public officials; legislators, county and local officials
12. government officials; federal, state, local
13. insurers; Medicare, Medicaid, Blue Cross, commercial insurers.

APPENDIX B

The Commonwealth of Massachusetts
Executive Office of Human Services
Department of Public Health
150 Tremont Street
Boston 02111

BAILUS WALKER, Jr., Ph.D., M.P.H.
Commissioner

March 30, 1984

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jerome H. Grossman, M.D.
New England Medical Center
171 Harrison Avenue
Boston, Massachusetts 02111

NOTICE OF DETERMINATION OF NEED
PROJECT NUMBER: 4-3240
THE NEW ENGLAND MEDICAL CENTER (Hospital)
(Substantial Change in Service to
Provide Liver Transplantation
Services)

Dear Dr. Grossman:

At their meeting of January 24, 1984, the Commissioner and the Public Health Council, acting together as the Department, voted, pursuant to M.G.L. c. 111, s.25C and the regulations adopted thereunder, to approve the Hospital's application for Determination of Need. The application, as approved, provides for the development of liver transplantation services at Children's Hospital, Massachusetts General Hospital, New England Deaconess Hospital and New England Medical Center in a cooperative manner as the Boston Center for Liver Transplantation. There is no capital expenditure associated with the project. Operating expenditures are discussed in Condition #4.

This determination is subject to the following conditions, in addition to the terms and conditions set forth in DoN Regulation 105 CMR 100.551:

1) The approval is for a three-year demonstration project, effective upon approval by the Public Health Council. Continuation of liver transplant service beyond this three-year period will require that a DoN application be submitted no earlier than May 1, 1986 and no later than January 1, 1987. The Hospital can continue to perform liver transplants until the Council acts on the DoN application.

2) The criteria for recipient selection shall be as set forth in the application (Policy Section IV). The Commissioner of Public Health must approve all changes in these patient selection criteria. Future criteria will be reviewed in conjunction with state of the art techniques in transplantation, Task Force reports, evaluation of transplant experience, outcomes in terms of patient quality of life, and donor organ availability.

3) The Hospital, via the Boston Center for Liver Transplantation (BCLT), shall collect the clinical and cost data included in Attachments 3 and 4 to the Staff Summary, as well as data pertaining to patient characteristics from the discharge abstract, statistics on resource use by cost centers, data on clinical outcomes of transplant patients, data on patients evaluated and rejected and data on patients who were referred for evaluation but not evaluated. The Hospital via the BCLT will provide the Department with such other data as requested by the Commissioner. The Hospital, via the BCLT, shall also make available to the Department the original data and results of evaluative studies as the Commissioner may request.

4) Incremental operating costs which reflect new and unusual resources and increased intensity of services due to implementation of liver transplantation services should be allowed as exceptions to the Hospital's Maximum Allowable Cost. This incremental operating cost should be no more than $43,000 for an adult transplant. Pediatric incremental operating costs should be based on the agreement between the Hospital and Massachusetts Blue Cross. The operating costs associated with this approval are subject to review by the Rate Setting Commission in accordance with their policies and procedures.

5) The Hospital shall co-sponsor with the Department an evaluation of its liver transplant services contingent upon the obtaining of external funding. The Hospital and the Commissioner will jointly develop a proposal for this purpose no later than January 1, 1985 and the Hospital shall cooperate in identifying sources for such external funding.

6) The Hospital shall not consider ability to pay or insurance status in the evaluation and recipient selection process. Persons who are uninsured and persons who are insured via governmental programs (e.g., Medicaid and Medicare) shall have equal access to transplants.

7) The Hospital shall not reduce Medicaid intensive services or primary care services as a trade-off for liver transplants.

8) The Hospital shall not reduce the free care provided for non-transplant medical services below that provided during the 1982-83 fiscal year. The RSC inflation factors shall be applied to that year's free care level in determining the minimum free care level for non-transplant medical services during each subsequent fiscal year.

9) The Hospital will have the protocols for liver transplant reviewed, approved and monitored by its Institutional Review Board.

The reasons for the approval with conditions are as follows:

1) Liver transplantation has become an accepted modality of care with therapeutic results for some patients.

2) The Task Forces on Organ Transplantation and Liver Transplantation recommended a controlled, limited inauguration of liver transplantation.

3) A three-year approval will allow for evaluative study of the associated issues and a complete public reconsideration of the situation in three years. This allows an opportunity to reduce the number of providers if there is not demonstrated need for the existing level of services, if the transplantation outcomes are not favorable or if the Department otherwise believes that the number of providers should be reduced or eliminated. A demonstration is appropriate because there are substantial uncertainties involved in liver transplantation. Total need is unclear, the relationships between volume, quality of care and outcome are clouded by differences in selection criteria and survival rates are changing due to the introduction of Cyclosporin A. (See Condition #1)

4) The Hospital's comments on increased volumes of transplants and the heavy burden of providing liver transplants lead the Department to conclude that the phasing-in of hospitals could lead to inappropriate rationing and a continued reliance on emergency waivers.

5) Changes in recipient selection criteria could affect the expected volume of procedures performed as well as access to the procedure. In order to assure continued access to this service, the Department added Condition #2.

6) The Hospital has identified a large set of data to be collected including clinical and cost related information. Given the evaluative nature of the demonstration study, the Department may request additional data on the following: patients evaluated and rejected; those referred for evaluation but not evaluated; and resource utilization within and among the facilities. The Department will establish, in consultation with the Hospital, an appropriate survey document and timetable for data collection. This data collection will provide information for evaluation of the demonstration project, hence Conditions #3 and #5.

7) Some resources used in the provision of care to the liver transplantee are unique (Cyclosporin, liver acquisition and large quantities of blood), but others are similar to those consumed by the average patient differing in severity and degree.

Thus, the Hospital should be allowed reimbursement only for costs in excess of the Maximum Allowable Cost in the amount of the difference between the care of the average patient and the cost for liver transplant hospitalization. There is an advantage to permitting reimbursement for liver transplantation outside the MAC and in place of volume increases allowed under the MAC because these costs do not become part of the future base for reimbursement and thus can be linked to procedures actually performed. Hence Condition #4 allows a $43,000 exception to the Maximum Allowable Cost for adult transplants.

8) The Hospital in correspondence with the HSA has represented that if two or more recipients are equally matched, the patient with the greatest clinical need with the best appropriate match will receive the organ, hence Condition #6.

9) The Hospital has agreed that financial criteria will not be an inhibition to receipt of a liver transplant and has represented that Massachusetts residents will be accepted for transplantation in certain instances without full renumeration being available. There is a factor for free care in various third party arrangements and as of FY '85, Chapter 372 guarantees that the four hospitals will have 100% of bad debt and free care bill reimbursed as an allowable cost. Also most transplant patients will qualify for Medicaid under a "spend-down" provision, hence Conditions #7 and #8.

10) The preliminary recommendations of the Task Force on Organ Transplantation issued on January 5,1984 have recommended that the protocols for liver transplants be reviewed and approved by the Institutional Review Board, hence Condition #9.

This Determination was effective upon approval by the Council. The Determination is subject to the conditions set forth in Determination of Need Regulation 105 CMR 100.551 including sections 100.551 (C) and (D), which read in part:

> (C) ...such determination shall be valid authorization only for the project for which made and only for the total capital expenditure approved.
>
> (D) Such determination shall be valid authorization for (2) two years or such other period as the Department may specify. Such determination shall expire if not extended by the Department for good cause shown. Within such period of authorization, the holder shall make substantial and continuing progress toward completion. If substantial and continuing progress toward completion is not made, the authorization shall be subject to revocation by the Department pursuant to 105 CMR 100.700...

Please note that any party wishing to appeal the Department's action stated above must file a claim of appeal with the Health Facilities Appeals Board, Northeastern University School of Law, Room 240 KV, 400 Huntington Avenue, Boston, MA 02115, within fourteen (14) days of receipt of this Notice. Each Applicant must include a statement that the appeal is not knowingly interposed for delay and must comply with the Board's "Rules of Procedure" available upon request from the Board. A copy of any claim of appeal filed with the Board must be served upon this Department through its General Counsel, 150 Tremont Street, Boston, MA 02111.

FOR THE PUBLIC HEALTH COUNCIL

Barbara Corcoran
Secretary to the Council

BC/JG/sds

cc: Office of State Health Planning
The Health Planning Council of Greater Boston, Inc. (HSA IV)
Joanne Bluestone, Medicaid
Charles Fiske, Ten Taxpayer Group
David Frost, Ten Taxpayer Group
Anthony Monaco, M.D., Ten Taxpayer Group
Robert Vanasse, Ten Taxpayer Group
Wayne Woodford, Rate Setting Commission
John Chapman, Rate Setting Commission
DoN Compliance Director
Mary Murphy, Division of Health Care Quality
Louise Clough, Division of Health Care Quality
Decision Letter File
Public File
Joseph Fermano, Blue Cross
Joan Gorga, Department of Public Health

The Commonwealth of Massachusetts
Executive Office of Human Services
Department of Public Health
150 Tremont Street
Boston 02111

Bailus Walker, Jr., Ph.D., M.P.H.
COMMISSIONER

September 28, 1984

Jerome H. Grossman, M.D.
New England Medical Center
171 Harrison Avenue
Boston, MA 02111

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Re: Liver Transplantation Service:
Notice of Determination of Need
DoN Project #4-3240

Dear Dr. Grossman:

In accordance with the Health Facilities Appeals Board action of August 29, 1984, the Commissioner and the Public Health Council, acting together as the Department voted, at their meeting of September 24, 1984, pursuant to M.G.L. c.111, ss.25C and 25E, to include four (4) additional conditions to the above referenced Determination of Need. The conditions (6 through 9) are as follows:

6. For Massachusetts residents, the Hospital shall not consider ability to pay or insurance status in the evaluation or recipient selection process. Massachusetts residents who are uninsured or are insured via governmental programs (e.g., Medicaid and Medicare) shall have equal access to transplants. Free care will be provided to non-Massachusetts residents in accordance with existing hospital free care policies.

7. The Hospital shall not reduce Medicaid intensive services or procedures or primary care services or procedures as a trade-off for liver transplants.

8. The Hospital shall not, as consequence of its undertaking a liver transplantation program, reduce the amount of free care provided to non-liver transplant patients below the amount provided during its 1983 fiscal year, as adjusted for inflation.

9. The Hospital will have its liver transplant protocols, including consent and withdrawal of consent policies, organ procurement policies,

recipient selection policies and confidentiality policies, reviewed and approved by an ethics committee of the Boston Center for Liver Transplantation, which will contain significant public representation, or by a special board set up for this purpose by the Department of Public Health.

The reasons for the inclusion of the conditions are as follows:

1. The Boston Center for Liver Transplantation will be a statewide and a New England resource. As the only liver transplant program presently operating in the upper New England area it is important that access to the program be available to all. However, while the Boston Center for Liver Transplantation has an obligation to serve residents from other states because organ procurement activities will occur throughout the area, Massachusetts residents should not subsidize their care. This distinction between Massachusetts and non-Massachusetts residents is in accordance with the Preliminary and Final Recommendations of the Organ Transplant Task Force.

2. Introduction of high cost services such as transplantation has the potential for causing cut-backs in other hospital services. The Task Force on Organ Transplantation in both their preliminary and final recommendations emphasized the importance of maintaining the level of existing high priority health care services and procedures to the public while introducing transplantation. The Department recognizes that factors other than the introduction of liver transplantation may cause the hospital to alter its provision of Medicaid intensive or primary care services. Therefore, condition 7 relates only to reductions which occur as a consequence of implementation of liver transplants.

3. Hospitals have historically allocated a part of their budget to free care. Introduction of a high-cost service such as liver transplantation should not be done at the expense of free care available for other services. The Department does recognize that a number of factors other than transplantation could result in the reduction of free care; for example, changes in case-mix or in the general economic climate. Therefore, condition 8 relates to reductions which occur as a consequence of implementation of liver transplants. The Department anticipates that changes in arrangements for third-party free care reimbursement effective October 1, 1984, will facilitate implementation of this condition.

4. The ethics of transplantation are an important consideration and are one of the main reasons for state involvement in the issue. It is important that one ethics committee for the Boston Center for Liver Transplantation be formed to review pertinent issues and to assure uniform, ethical liver transplantation policies in member hospitals. Public representation on this ethics committee will provide for a

broader spectrum of opinion and discussion than a more limited institution based body.

This determination is effective upon receipt. The Determination is subject to the conditions set forth in the Determination of Need Regulation 105 CMR 100.551, and conditions 1 through 5 as set forth in the Notice of Determination of Need for the project dated March 30, 1984.

Please note that any party wishing to appeal the Department's action stated above must file a claim of appeal with the Health Facilities Appeals Board, Northeastern University School of Law, Room 240 KV, 400 Huntington Avenue, Boston, Massachusetts 02115, within fourteen (14) days of receipt of this Notice. Each Applicant must include a statement that the appeal is not knowingly interposed for delay and must comply with the Board's "Rules of Procedure" available upon request from the Board. A copy of any claim of appeal filed with the Board must be served upon this Department through its General Counsel, 150 Tremont Street, 9th Floor, Boston, Massachusetts 02111.

FOR THE PUBLIC HEALTH COUNCIL

John B. O'Donnell
Acting Director
Determination of Need Program

JBO/lsh
cc: Office of Health Policy
The Health Planning Council of Greater Boston
Joanne Bluestone, Medicaid
Charles Fiske, Ten Taxpayer Group
David Frost, Ten Tax Payer Group
Anthony Monaco, M.D., Ten Taxpayer Group
Robert Vanasse, Ten Taxpayer Group
Wayne Woodford, Rate Setting Commission
John Chapman, Rate Setting Commission
DoN Compliance Director
George Annas, Chairman, Organ Transplantation Task Force
Jack Eiferman, Legal Office
Mary Murphy, Division of Health Care Quality
Louise Clough, Division of Health Care Quality
Decision Letter File
Public File
Joseph Fermano, Blue Cross
Joan Gorga, Department of Public Health

APPENDIX C

The Commonwealth of Massachusetts
Executive Office of Human Services
Department of Public Health
150 Tremont Street
Boston 02111

BAILUS WALKER, Jr, Ph.D, M.P.H.
Commissioner

May 16, 1984

H. Richard Nesson, M.D.
President
Brigham and Women's Hospital
75 Francis Street
Boston, Massachusetts 02115

Re: Cardiac Transplantation

Dear Dr. Nesson:

I have considered your request for a one year special project exemption from the Determination of Need (DoN) requirements pursuant to Section 105 CMR 100.308 to permit Brigham and Women's Hospital (Hospital) to perform cardiac transplantation procedures and have decided to approve your request for an exemption, subject to the following conditions:

1. The exemption for this demonstration project is effective immediately and shall remain in effect only until January 1, 1985.

2. The criteria for recipient selection for cardiac transplants shall be as set forth in the Hospital's Proposal to Massachusetts Blue Shield on pp. 166 and 167. Age over 50 and the absence of a supporting family structure shall not be absolute contraindications but will be one of several factors for evaluation. The DoN Program Director must approve all changes in these patient selection criteria.

3. The Hospital shall accept all qualified Massachusetts patients into the cardiac transplant program without regard to the patient's hospital and physician affiliation.

4. The Hospital shall collect at a minimum the following data:

   - clinical cost data
   - data pertaining to patient characteristics from the discharge abstract
   - statistics on resource use by cost centers
   - data on clinical outcomes of transplant patients
   - data on patients evaluated and rejected
   - data on patients referred for evaluation but not evaluated.

The Hospital will also provide the Department with such other data as requested by the Program Director, in such format and time table as requested. The Hospital will make available to the Department all original data and results of all evaluative studies performed as the Program Director may request.

5. The Hospital shall be obliged to support the operating expenses for cardiac transplantation within current reimbursement limits as set by the Hospital's Maximum Allowable Cost under current legislation (Chapter 372 of the Acts of 1982).

6. The Hospital shall not consider ability to pay or insurance status in the recipient selection process. Persons who are uninsured and persons who are insured via governmental programs shall have equal access to transplants.

7. The Hospital shall not reduce Medicaid intensive services or primary care services as a trade-off for heart transplants.

8. The Hospital shall not reduce the non-transplant amount of free care provided below that of the 1982-83 fiscal year as increased by the Rate Setting Commission inflation index.

9. The Hospital shall have the protocols for heart transplant reviewed, approved and monitored by its Institutional Review Board.

The Department looks forward to working with you on cardiac transplantation and will contact you in regard to the very important data collection effort.

Very truly yours,

Steven Sauter
Director

SS/sds
cc: Ruselle Robinson, General Counsel
Section 100.308 File
Joan Gorga, Policy and Planning
Steven Shufro, Assistant Commissioner
Future DoN File
HSA IV
Wayne Woodford, Rate Setting Commission
Joanne Bluestone, Medicaid
Jon Kingsdale, Blue Cross